VOLUME 13 NUMBER 9

Food·Drug·Cosmetic Law Journal

SEPTEMBER • 1958

Hawaii's Food and Drug Laws . . . . .
GEORGE H. AKAU

Cosmetics, Chemicals and Claims . . .
GEORGE P. LARRICK

Closing the Gap in Label Legislation . .
BERNARD E. CONLEY

A COMMERCE CLEARING HOUSE PUBLICATION

PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . September, 1958

		Page
Reports to the Reader		
About the Authors . . . Meetings of Food and Drug Men		547
Washington—Action and News In the Food and Drug Administration . . . In the Federal Trade Commission		549
Hawaii's Food and Drug Laws	George H. Akau	551
Cosmetics, Chemicals and Claims	George P. Larrick	564
Closing the Gap in Label Legislation	Bernard E. Conley	570
Christopher Comments	Thomas W. Christopher	590
The Scientists' Forum	Bernard L. Oser	592

VOLUME 13 NUMBER 9

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REPORTS

TO THE READER

About the Authors

George H. Akau, who presents an interesting history of the food and drug laws of Hawaii in this September JOURNAL, is food commissioner and analyst for the Territory of Hawaii. Born in Hilo, he attended St. Mary's School and St. Louis College, and was awarded a B. S. degree in sugar technology (1935) and an M. S. degree in chemistry (1937) by the University of Hawaii, at Honolulu.

Mr. Akau served as a chemist with the United States AAA taro program at Honolulu in 1935 and 1936; as assistant instructor and research fellow with the university in 1936 and 1937; and as chemist for several fruit-product companies from 1937 to 1939. He became police chemist for the Honolulu Police Department in 1940, and in 1943 went on to a position as superintendent-chemist for Pacific Rectifiers, Honolulu. In 1944, he became chief of the Bureau of Pure Food and Drugs of the Territorial Department of Health of Hawaii and also assumed the post of territorial food commissioner and analyst.

Since 1946, Mr. Akau has been acting Chief of San Francisco District, United States Food and Drug Administration. He is a patentee of food processes and machinery.

George P. Larrick, of Washington, D. C., is United States Commissioner of Food and Drugs, Department of Health, Education, and Welfare. His excellent article "Cosmetics, Chemicals and Claims," is derived from an address which he delivered at the annual convention of The Toilet Goods Association, Inc., at Poland Spring, Maine, on June 26.

He succeeded the late Charles W. Crawford as Commissioner in 1954, after serving as Deputy Commissioner for three years. A career employee of FDA for more than 35 years, Mr. Larrick joined the agency as an inspector. Successively, he was administrative assistant, from 1928 to 1930; senior inspector from 1930 to 1939; Chief Inspector from 1939 to 1945; and Assistant Commissioner from 1945 to 1948. He was named Associate Commissioner in 1948, and held that post until he became Deputy Commissioner.

Commissioner Larrick attended Wittenberg College, Springfield, Ohio, and The Ohio State University, as well as George Washington University, where he specialized in chemistry and biology. He is a native of Springfield.

Bernard E. Conley, secretary of the committee on toxicology of the American Medical Association writes on the subject of uniform legislation concerning the labeling of hazardous substances. His study is a comparison of two model bills, one of them drafted by the AMA.

The writer of the feature "Christopher Comments" is **Thomas W. Christopher,** associate dean and professor of law at Emory University, in Georgia.

"The Scientists' Forum" is edited by **Bernard L. Oser,** who is director of Food and Drug Research Laboratories, Inc., New York City. This month the "Forum" features an address, "Safety

Evaluation Procedures and Interpretations," presented by **Henry F. Smyth, Jr.**, of the Mellon Institute, Pittsburgh, Pennsylvania, at the annual meeting of the Institute of Food Technologists held at Chicago last May. Dr. Smyth's paper was delivered in a panel discussion of important current aspects of food additives.

Meetings of Food and Drug Men

American Bar Association—Division of Food, Drug and Cosmetic Law.—At the 1958 meeting of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, American Bar Association, Charles Wesley Dunn was re-elected chairman of the division. Edwin L. Harding, vice president and general counsel for Kellogg Company, was re-elected secretary. The meeting was held on August 26 at the University of Southern California School of Law, University Park, Los Angeles.

Association of Official Agricultural Chemists, Inc.—Government chemists will discuss law-enforcement methods at the seventy-second meeting of the Association of Official Agricultural Chemists, to be held at the Shoreham Hotel, Washington, D. C., October 13-15. The AOAC was founded in 1884 to provide reliable methods of analysis required for the enforcement of pure food and drug laws and also laws regulating the sale of other agricultural commodities such as fertilizers, feeds and pesticides. At these annual assemblies, professional scientific workers in the federal and state agencies who are concerned with enforcing laws and regulations dealing with agricultural commodities meet with the scientists of the regulated industries.

Nearly 1,000 persons are expected to attend the 1958 meeting. Some of the different fields of interest (more than 50 in number) to be covered are detection of adulteration of vanilla extracts by paper chromatography; identification of preservatives in foods; chemical method for vitamin D; gas chromatographic methods; shellfish poison; decomposition in fish; and available phosphorus in fertilizers.

All sessions are open to interested scientific workers and to the public. Copies of the program will be available about October 1 from the secretary, William Horwitz. Dr. Horwitz' address is: Box 540, Benjamin Franklin Station, Washington 4, D. C.

The AOAC meeting will be followed by meetings of the American Feed Control Officials, Fertilizer Control Officials, and Pesticide Control Officials. These organizations are concerned with state and federal laws and regulations dealing with the specialized commodities.

Changes in radioactivity of foods since the preatomic era will be reported at the general meeting. Edwin P. Laug and Wendell C. Wallace, of the United States Food and Drug Administration, have tested hundreds of samples of foods known to have been packed before and after the first atomic explosion in 1945. Some of the pre-1945 specimens were collected from pantries all over the country. Others were obtained from supplies left by early antarctic explorers, including the Shackleton expeditions of 1909-1913 and the Byrd expedition of 1939. The data will be analyzed to show whether or not radioactivity has increased in the recent samples.

"Food Additives" will be the topic of the annual address of the president of the AOAC, Frank A. Vorhes, Jr., of FDA.

An entire session will be devoted to discussion of the mysterious "chicken edema disease."

WASHINGTON-

ACTION AND NEWS

In the Food and Drug Administration

New Food-Additives Law Enacted.—The Food and Drug Administration's September report on enforcement and compliance announced that a new and important amendment to the federal food law went into effect on September 6, when President Eisenhower signed a bill (H. R. 13254, Eighty-fifth Congress) requiring the safety of food additives to be established before such chemicals can be used in food or feed for humans or animals. Public Law 85-929, 72 Stat. 1784, which "is also intended to advance food technology by permitting the use of food additives at safe levels," follows, in full text:

"AN ACT

"To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit use in food of additives which have not been adequately tested to establish their safety.

"*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That this Act may be cited as the 'Food Additives Amendment of 1958'.

"SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"'(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"'(1) a pesticide chemical in or on a raw agricultural commodity; or

"'(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"'(3) any substance used in accordance with a sanction or approval granted

prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

"'(t) The term "safe," as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal.'

"SEC. 3. (a) Clause (2) of section 402(a), as amended, of such Act is amended to read as follows: '(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;'.

"(b) Section 402(a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: 'or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409'.

"(c) The first sentence of section 406(a) of such Act is amended by striking out 'clause (2)' wherever it appears in such sentence and inserting in lieu thereof 'clause (2)(A)'.

"SEC. 4. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"'FOOD ADDITIVES

"'Unsafe Food Additives

"'SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

"'(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"'(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

"'While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402(a).

"'Petition To Establish Safety

"'(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

"'(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"'(A) the name and all pertinent information concerning such food addi-

(Continued on page 602)

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HAWAII'S FOOD AND DRUG LAWS

By GEORGE H. AKAU

The Author Traces a Laudable History of Regulatory Controls of Food and Drugs Which Have Spanned More Than 100 Years, Beginning with the "Market Law for the City of Honolulu," Which Was Signed by King Kamehameha III in November, 1850

KING KAMEHAMEHA III, to cope with the cholera and smallpox epidemics that were then plaguing many countries of the world and Hawaii, established a board of health on December 13, 1850. This board of health is one of the oldest in the United States.

Geographically, the chain of eight islands which constitute the Territory of Hawaii lies about 2,100 miles west of San Francisco in about the same latitude as Mexico City. The largest island of Hawaii has an area twice that of Delaware, or 4,030 square miles, while the other islands range from 250 to 720 square miles. The territory has a total land area in excess of that of Connecticut, or 6,435 square miles, with a total population of 516,878. Over three fourths of the population, or 375,000, reside on the Island of Oahu, where the capital of Honolulu is located.

The history of Hawaii began with the discovery of the islands by Captain James Cook in 1778. In 1810 the Kingdom of Hawaii was

Mr. Akau Has Served as Food Commissioner and Analyst, Territory of Hawaii, Since 1944

established by King Kamehameha I, the military genius from the Island of Hawaii. This monarchy continued until 1893, when revolutionists deposed Queen Liliuokalani and established a provisional government. This government was followed by the Republic of Hawaii in 1894. On July 7, 1898, President McKinley signed the annexation resolution making Hawaii an integral part of the United States. The territorial form of government went into effect on June 14, 1900.

Following Captain Cook's discovery, the territory became, in order, a wintering place and point of supply for American whalers operating in the North Pacific, an exporter of sandalwood to the Orient and, finally, an agricultural economy based on the production of sugar and pineapple.

The first time that any reference was made to foods in the laws of the Kingdom of Hawaii appeared under a law entitled "Market Law for the City of Honolulu." This law, which was enacted by the House of Nobles and Representatives of the Hawaiian Islands in the legislative council and signed by King Kamehameha on November 6, 1850, set aside a new stone building on the wharf at Honolulu and declared this to be the public market of Honolulu. Provision was made for the Governor of Oahu to appoint a clerk of the market. This appointee had various duties. Among these duties were:

> . . . to cause all dirt and filth which may accumulate in said public market, to be removed daily, ... to assign and set apart certain portions of the land adjacent to the building designated as the public market, specifically, to each person in the order in which they may apply to him, for the purpose of exposing to sale, and selling the articles he may wish to expose for sale, and no person shall expose to sale or sell any fresh garden produce, meats, fish, or other articles for consumption, except under licenses, granted under the law of this

kingdom, which will permit Hawaiian produce to be sold at the places of business of persons so licensed, at or upon any regular stand, in any street or place within one mile from the public market, other than in the place or places set apart by the said clerk, or in the market building, under the penalty of ten dollars for every offense, it being understood that this section shall not prevent any person from hawking or peddling such articles for consumption as heretofore . . . to inspect and examine all the weights, measures and beams used in weighing and measuring in the public market. [*Note:* The early laws were both in Hawaiian and in English.]

An act to provide for licensing dairies, sale of milk and the inspection of milk in the City of Honolulu was approved by King David Kalakaua on August 5, 1882. The Minister of the Interior was the person authorized to issue a license amounting to $25 to anyone desirous of carrying on the business of dairying, and for the sale of milk. Two sections of this act are noteworthy. These were:

Section 3. Any person who shall sell or offer for public sale in Honolulu milk which has been adulterated by the addition of water, or any other substance, shall be deemed guilty of a misdemeanor, and, on conviction thereof, shall be punished by a fine of not less than five dollars, nor more than twenty-five dollars.

Section 4. The Agent of the Board of Health shall appoint one of its agents for the city of Honolulu to be Inspector of Milk. It shall be the duty of such Inspector to inspect from time to time milk sold or offered for sale in Honolulu. Said Inspector is hereby empowered, when he shall find milk which has been adulterated, to take and confiscate the same forthwith; and it shall be his duty to institute prosecutions therefor.

Two days later, on August 7, 1882, King Kalakaua approved an act to regulate the sale of spirituous liquors. Section 31 of this rather lengthy document referred to the prohibition against adulterating of spirituous liquor. It provided for a penalty of from $100 to $500 for any licensed person selling adulterated liquor. It also provided for the analysis of such liquor on the authorization of any justice and on the complaint of anyone who deposited five dollars, which was employed to defray the expense of the analysis by a competent person.

The need for the adoption of certain statutes and amending others moved the president of the board of health in his report to the Legislature of the Hawaiian Kingdom in 1892 to comment as follows:

What I have said of wash houses can also be said of poi factories, a nuisance when carried on even under the best conditions of cleanliness and order. Many complaints have been made relative to them, reports have been ordered made, and nothing has been done beyond that, for lack of statute.

The president further complained that the clerk of the market had no authority to destroy fish or meat unfit for human food. He recommended that the power of condemnation of unsound food be

granted to the clerk because it was well known that, not infrequently, unfit food "has been freshened up by some process to make it appear less bad than it is."

1898—Pure Food and Drug Law Adopted

It is interesting to note that on May 16, 1898, the Republic of Hawaii adopted a pure food and drug law, and established the position of food commissioner and analyst to enforce that act.[1] While communications were slow in those days of sailing vessels, it is not unlikely that news of the agitation by Dr. Harvey Washington Wiley and his supporters for legislation to correct the food and drug abuses of that day spurred the legislators of the Republic of Hawaii into adopting a food and drug law.

Dr. Edmund C. Shorey, the first food commissioner, was appointed on or about May 1, 1899, although the budget had provided funds for filling this position as early as August 1, 1898. During the first eight-month period of the "food commissioner's office," Dr. Shorey not only examined 710 samples of various foods—mainly milk—but visited 37 dairies and prosecuted 13 food dealers. Fines imposed totaled $280. Dr. Shorey resigned as food commissioner and analyst to become chemist of the United States Experiment Station in Honolulu. R. A. Duncan, appointed on October 1, 1903, died in office in 1910.

In his biennial report ending December 31, 1899, Dr. Henry F. Cooper, then president of the board of health wrote:

> . . . good work has been done by our Food Commissioner, more especially in the District of Honolulu in the prevention of the adulteration of milk. His work is now being extended so as to include the other important articles of food. He has also given attention to the presence of salicylic acid in beers and catsups. Work along these lines, while but little appreciated by the general public, should be encouraged. It is one of those thankless tasks which are necessary for the reason that many of our people are so indifferent to their own welfare as to care little for work of this nature, but the purity of our food stuffs and drink is a matter of great concern, especially in those articles which are consumed by young children.

On December 31, 1899, Dr. W. T. Monsarrat, veterinary surgeon and meat inspector, reported on inspections at slaughterhouses for the biennium ending December 31, 1899. During this time 15,841 bullocks, 2,698 calves, 20,251 sheep and 15,821 hogs were examined. There were 43 animals and various organs condemned as unfit for consumption.

In outlining the work of the food commissioner, the president of the board of health in his report of the period from November 19,

[1] See appendix at end of this article.

1900, to February 1, 1901, pointed out that the food commissioner had been greatly hampered by defects in the law concerning adulterated foods. He also stated that proposed amendments to the food law had been submitted to the attorney general for study.

In his 1904 report, the president of the board of health emphasized that the importance of the food commissioner's position was well appreciated and that the people would place more power in the food and drug department for their own good as they began to realize the necessity of protecting themselves against dangerous and deleterious food and drink.

The need for more stringent dairy laws in 1906 moved Food Commissioner Duncan to report that he had taken the initiative in conducting a sanitary survey of the dairies. He and his assistant sanitary inspector, a Mr. Myhre, spent three weeks in this work and many needful improvements were made. He bemoaned the lack of a law or regulation covering the sanitation of dairies and recommended that the incoming legislature enact dairy legislation which would regulate the production and distribution of milk.

In the following year, Commissioner Duncan reported that he had investigated a number of illnesses caused by milk traceable to a single dairy. After recommendation that this dairy thoroughly clean and sterilize buildings and utensils, no new cases of illness appeared. Mr. Duncan wrote to Dr. Wiley, Chief of the United States Bureau of Chemistry, concerning the contaminated milk incident and the illness caused, and requested Dr. Wiley's opinion. This letter was referred to Dr. A. D. Melvin, Chief of the Bureau of Animal Industry, who then wrote Commissioner Duncan.

Noteworthy is Mr. Duncan's reference to the nonadmission of the *United States Pharmacopoeia* as evidence. Of the various foods that he had examined and his findings (1907 report), he stated:

> Forty-six samples, consisting of whiskey, brandy and wine were submitted by the Treasurer of the Territory under the provision of Act 67, Session Laws of 1905. Six prosecutions were made by the Treasurer for the sale of adulterated liquor but on account of the non-admission of the United States Pharmacopoeia as evidence, upon which the Territorial liquor standards are based the cases were dismissed.

As a side interest, mention should be made that the first apparatus for commercially pasteurizing milk in the Territory of Hawaii was installed in Honolulu in 1906 by the dairymen's association. This installation antedated the first commercial pasteurizer in the United States in New York City by one year. A number of milk-borne dis-

eases reported in 1906 probably encouraged local dairymen to become interested in the pasteurizing process.

Dr. Edward B. Blanchard was appointed July 20, 1910, as food commissioner. He resigned on June 12, 1913. A. W. Hansen's appointment followed, on July 1, 1913. He carried on his duties until December 31, 1918, when he resigned to return to the United States Department of Agriculture's Bureau of Chemistry, on the mainland.

In 1912, the food commissioner reported on the food laws which provided for food standards. He stated that the territorial legislature had created standards for cream, ice cream, and poi. It seems that many dealers had ignored the legal standard for ice cream, and several prosecutions were necessary before the work began to be effective. Commissioner Blanchard, fearing that an attempt might be made to lower the ice cream standard, recommended that a public test of ice creams be made in order to have data to place before the legislature.

Beginning with June, 1913, an arrangement was made between the Territory of Hawaii and the United States Bureau of Chemistry, whereby half the salaries of the food commissioner and his staff (stenographer and laboratory assistant) were paid by the territory and half by the federal government. In 1916, M. B. Bairos was appointed food commissioner. In 1917, the chief sanitary inspectors on the neighbor islands of Hawaii, Maui and Kauai were appointed as deputy food commissioners. This practice has continued up to the present time, since the Food and Drug Administration maintains no full-time employees on these islands.

Food Commissioner Hansen, in 1914, wrote about utilizing the federal law in inspections, weights and measures and about the need for regulation relative to the washing of soda-water bottles. He reported that inspection under the federal law of import foods and drugs had proceeded satisfactorily and that wholesale and retail merchants had been keeping their goods in strict conformity with national and territorial food and drug requirements, including net-weight and measure provisions, as well as the elimination of the guaranty legend from labels. (This is the first time that reference is found relative to the policy of enforcement of both federal and territorial food and drug requirements.) Commissioner Hansen recommended that the board of health adopt a regulation covering the washing of bottles in soda works because the prevailing practice was most inadequate and dangerous to the public health.

Again, in his report of 1916, the food commissioner expresssed the feeling that special investigations made of taro, milk, cold-storage plants, storage eggs, oranges and foods found in ice boxes of stores and restaurants required amendments to the food laws.

The "pure food bureau" was requested to make an investigation into the causes for existing high prices of foodstuffs in April of 1917. This data was obtained in order that the president of the board might comply with House Resolution No. 106 of the territorial legislature. The food commissioner reported that attention had been given to foodstuffs imported from the mainland and that violations were reported to the federal food authorities at San Francisco so that the matter could be taken up at the source.

Under the heading "Pure Food Bureau," it was noted that Food Commissioner Hansen, who was also the federal representative of the Department of Agriculture, resigned his position to return to the mainland on account of his family. Mr. Bairos, who had been his assistant, was appointed to fill the vacancy. The report also noted that conditions arising since the outbreak of the war (World War I) had increased the importance of the bureau and greatly increased the amount of work to be performed. Close assistance and cooperation had been given the United States Department of Agriculture and the United States Food Administration, and a great deal of time had been devoted to the inspection of bakeries to see that the federal baking rules were being followed.

New laws in regard to bread and ice cream were passed by the 1919 legislature. Act 176, on bread, provided that loaves shall be manufactured in certain definite net weights with limited variations, similar to the regulations enforced by the United States Food Administration during the war. Act 236, relating to ice cream, set forth that any wholesome dairy product not containing 14 per cent of butterfat could be sold as "ice milk," "frozen sweets" or "frozen dainty," provided that the proper signs, tags or posters, as described by the act, were properly exhibited on the receptacles, delivery wagons, and premises. The food commissioner wrote:

> This Act is in harmony with the requirements in reference to labeling food and drug products in general. The label on an article of food or drugs must contain no statement which may mislead or deceive the purchaser. The label must set forth the true nature of the product, i.e., an article must not be sold for that which it is not. These new laws have been explained in detail to the

various dealers and we believe it is but a matter of time until they will be complied with in every respect.

The 1919 report noted that the pure food bureau was able to keep in close touch with the quality and sanitation of the food supplies of restaurants, bakeries, markets, stores, dairies and poi shops through the work of the bureau's food inspector and the assistance of the city and county (Honolulu) milk and poi inspectors.

In 1920, the food commissioner observed that the bread-weight inspections, relative to Act 176, Session Laws of Hawaii 1919, had had a salutary effect upon the net weight of the loaf and upon the quality of the bread.

He recommended that a law be enacted requiring that no milk, at any time during the process of its preparation, give a count of over 500,000 bacteria per cubic centimeter nor that it give a count of over 250,000 bacteria per cubic centimeter at the time of its delivery to the customer nor that cream, at the time of its delivery, give a count of over 500,000 bacteria, in accordance with the then-standard methods adopted by the American Public Health Association.

In his report to the Governor of Hawaii in 1922, the president of the board of health observed:

> Since the influenza epidemic of several years ago special attention has been given to the washing and sterilizing of soda-water bottles. All of the soda-water companies operating in Honolulu are now equipped with bottle-washing machines in which the bottles are soaked in an alkaline solution.

It will be recalled that Food Commissioner Hansen had urged the board of health to adopt regulations for a more adequate sanitizing of empty soda-water bottles eight years earlier.

The "pure food and drug bureau" had been increasing its investigations and inspections of dairies and milk supplies as a result of greatly increased interest shown by the community in the question of producing clean milk.

In the annual report for 1924 of the president of the board of health, we find the following comments by the food commissioner:

> Shortly after the adoption of the new dairy and milk regulations by the Territorial Board of Health, at the beginning of the year, the organization of this department was somewhat modified so that practically all the dairy and milk inspection work on the Island of Oahu was placed under the supervision of this Bureau. Two inspectors, allowed the sanitary department by the last legislature, were transferred to this department and assigned the duties of dairy and milk inspectors in our "Dairy Division," thus created. [*Note:* This division was transferred to the sanitary inspectors' office on October 6, 1925. Scoring of dairies, however, remained a responsibility of the pure food and drug

bureau.] Also the Health officials of the City and County of Honolulu arranged to have their milk inspector work under the direct instructions of this Bureau, and later in the year, a trained laboratory technician was appointed by the County Board to assist in our milk analytical work. With this additional force, this office has endeavored to keep a check on the milk supply of Oahu.

During the year a general campaign for better, safer and the consumption of more milk was instituted, in which many citizens, organizations and the press took a very active part. As what has been stated, the aim of all health officials, as well as milk producers' organizations, is the production and sale of milk which is safe for human consumption, so that consumers may have full confidence in the milk which is offered them and may use larger quantities of this most important food. All grades of milk, therefore, should be safe milk. Milk is liquid food, containing food elements, either in solution or suspension, and makes an ideal medium for bacteria, both harmful and unharmful. If these organisms are of a disease producing kind, serious epidemics may result, and milk has been found to be the cause of typhoid fever, tuberculosis, and numerous other conditions. Every avenue of infection of milk supplies, from the farm to the consumer, must be controlled.

In accordance with a cooperative arrangement by the county and territorial health officials in 1938, the food inspectors of the City and County of Honolulu were assigned to work under the direction of the pure food and drug bureau.

The new territorial egg law, with suitable board of health regulations, became effective on March 19, 1932. That same year the bureau started the enforcement of the new poison act and regulations adopted by the board of health.

The legislature of 1933 combined the bureau of pure foods with the bureau of sanitation under the title of "bureau of sanitation and pure food" upon the recommendation of the bureau of government research. A subdivision of this combined bureau setup was the food and drug division, headed by Food Commissioner M. Benjamin Bairos. In 1935, the bureau was separated from the bureau of sanitation and was restored to its original status.

In order to halt violations of the territorial egg laws and regulations in 1936, it was necessary to call upon the Federal Emergency Relief Administration for assistance. In the enacting of the egg laws the legislature had not provided for any additional personnel for the enforcement of these laws.

Apparently, Commissioner Bairos felt that his efforts in enforcing the egg laws were not being appreciated, for he wrote as follows:

From a public health standpoint, criticism is sometimes made that considerable work done by food and drug bureaus, has only a limited public health significance. It may be stated that while both our food and drug laws and those of the Federal Administration have important health purposes, they are also strongly agricultural and economic in character. The laws are designed not only

to protect the consuming public from personal injury through consumption of harmful foods and dangerous drugs, but also to protect the purchasing and business public from economic injury by deceitful sales and unfair competition. Violations which involve economic cheats mean financial loss to the consumer, and their regulation is a matter of great importance.

In 1937, continued efforts were made to enforce the territorial egg laws and regulations with assistance from the Works Progress Administration. Dairy regulations were revised and adopted during the year with the exception of provisions relating to the grading of milk. The grading requirements of the old regulations were continued. Much time was spent in checking on the operation of fountains, cafes and hotels relative to a new regulation requiring that milk be served in original bottles as received from the dairy producer or distributor. It was observed that some difficulty was encountered in obtaining conformity with the new regulations requiring that the entire mixes of ice cream and other frozen products be pasteurized before freezing, because many of the smaller concerns were not equipped with pasteurizers.

The 1939 Legislature of Hawaii transferred the power of enforcing the egg laws from the board of health to the board of commissioners of agriculture and forestry, the belief being that the egg laws and regulations, particularly in reference to stamping and grading, were mostly commercial measures of little public-health significance.

1941—Enactment of Hawaii Food, Drug and Cosmetic Act

The territorial legislature in 1941 enacted the Hawaii Food, Drug and Cosmetic Act, which was closely patterned after the Federal Food, Drug, and Cosmetic Act. Objectives of this law, as with the previous one, were to prevent the manufacture and sale of adulterated or misbranded foods, drugs, devices and cosmetics, and the false or misleading advertising of such commodities.

In commenting on the first year of operation under the new law, Mr. Bairos wrote, in 1942:

The fiscal year ending June 30, 1942 was the first in which the Pure Food and Drug Bureau operated under the new Hawaii Food, Drug and Cosmetic Act of 1941. In compliance with the wishes of the legislators when enacting the statute, our efforts in the enforcement of the act during the year, have been mostly of an educational and exploratory nature, where new labeling requirements were concerned, in order to afford manufacturers and packers sufficient time to make proper adjustments. No definitions and standards of identity for foods were promulgated on account of delays due to the war emergencies. Many of the federal definitions and standards have not yet been established.

During 1943, regulations were promulgated by the board, fixing and establishing definitions and standards of identity of milk, ice cream, ice milk, frozen sweets, and poi. In 1950, the regulations were revised to include various meat-food products, as well as foods for which definitions and standards of identity had been promulgated by the United States Food and Drug Administration.

Food Commissioner and Analyst Bairos retired on November 30, 1943, after spending 27 years in the territorial pure food and drug field. George H. Akau succeeded Mr. Bairos as food commissioner and analyst on January 1, 1944.

At its regular meeting on December 12, 1943, the board of health had decided to place the bureau of pure food and drugs administratively under the bureau of sanitation. This change became effective on January 1, 1944. At a later date these administrative units became known as "bureau of pure food and drugs" and "division of sanitation," respectively.

During 1944, a new regulation pertaining to the peddling of medicines, drugs and devices was passed. This regulation made the qualifications for itinerant vendors more stringent and also gave the board of health control of not only medicine and drug peddlers, but peddlers of devices such as hearing and asthmatic aids as well.

By an act of the territorial legislature in 1945, a sizable appropriation was made to support the food and meat inspection positions which were transferred from the City and County of Honolulu to the bureau of pure food and drugs, beginning July 1, 1945. Prior to this date, the fish, poi and meat inspection staff of the City and County of Honolulu, although paid out of county funds, was administered by the food commissioner. These positions had been under the health office of the City and County of Honolulu. The inspectors were employed to enforce the municipal ordinances relative to meat, fish, and other foods. The transfer of these positions to the territory streamlined the administration of this important section of food inspections.

In 1945, the staff of the bureau consisted of 14 persons. These were: food commissioner and analyst; laboratory technician; food and drug inspector; stenographer; typist; public-health veterinarian; two food inspectors; five meat inspectors; and one food sanitarian. In April, 1946, a chemist was added to the staff.

In August, 1947, the bureau of laboratories was created by the board of health. Transferred from the bureau of pure food and drugs

to the new bureau were chemist, laboratory technician, and food sanitarian. On July 10, 1950, the position of narcotics investigator, which was authorized by the 1949 legislature, was filled. The investigator was to give proper attention to the enforcement of the uniform territorial narcotic act, which previously had been left to the police to enforce as best they could.

Since the end of World War II, bureau personnel have carried on the work of the United States Food and Drug Administration's San Francisco office because the Administration maintains no office in Hawaii. Most of this work consists of inspecting foreign imports, sampling, forwarding import samples to the San Francisco office for analyses, and taking administrative action. This cooperative effort has proved to be very effective in keeping out adulterated and misbranded foreign foods, drugs, devices and cosmetics.

In 1948, following a resumption of commerce with foreign countries, items representing a value of $80,000 were denied entry in Honolulu because of adulteration with saccharin, salicylic acid, nonpermitted coal-tar dyes, rodent hairs, whole insects or insect parts. In recent years, import condemnations have been closer to $9,000 per year. These actions have been taken in conjunction with enforcement of the Federal Food, Drug, and Cosmetic Act by personnel of the bureau of pure food and drugs.

Narcotic Laws—1953 Amendment

The 1953 legislature, because of the rising incidence of narcotics addiction in Hawaii following World War II, amended the narcotic laws considerably. It also created a section for narcotics control within the office of the food commissioner. Provision was made for two narcotic investigators and a clerk. Except for one narcotics investigator, these positions were never filled.

The same legislature also enacted a territory-wide meat inspection act enforceable by the board of commissioners of agriculture and forestry. Pursuant to this act, seven bureau personnel—consisting of six meat inspectors and the public health veterinarian—were transferred from the bureau of pure food and drugs to the agriculture board. Also transferred were the two public-health veterinarians and one meat inspector on the Island of Hawaii, who had been paid out of bureau funds in the enforcement of the County of Hawaii meat-inspection ordinance since October, 1950.

The legislature, in 1955, passed two acts concerning narcotics. Act 257 established procedures for the compulsory treatment of drug addicts, while Act 180 amended the uniform narcotic act to define the drugs in the same manner as they are defined in the federal law.

Present Composition of Bureau

At the present time, bureau personnel are as follows: food commissioner and analyst, food and drug inspector, narcotics investigator, two food inspectors, stenographer and typist. Because of the small staff, the bureau was forced to give priorities to the more important aspects of the food and drug program and to co-ordinate its activities with those of other inspectional and investigational personnel of the department of health.

In addition to the enforcement of the Hawaii Food, Drug and Cosmetic Act, bureau responsibilities include enforcement of laws and public-health regulations relating to narcotic drugs; milk; frozen desserts; storage of fish; fishing on commercial vessels; manufacture of poi; sale of poisons; enrichment of bread and flour; refrigerated warehouses; weights and measures; itinerant vendors of drugs and devices; sale of prophylactics; oleomargarine; importation of toxic fishes; and medical practice. It is noteworthy that the Hawaii Food, Drug and Cosmetic Act includes a section prohibiting the false and misleading advertisement of foods, drugs, devices and cosmetics. It will be recalled that in the Congressional discussions (Charles Wesley Dunn, *Federal Food, Drug, and Cosmetic Act*) leading to the adoption of the amended federal statute of 1938, strong representations had been made for the inclusion of a section prohibiting the false or misleading advertisement of foods, drugs, devices and cosmetics. The Federal Trade Commission was given the task of combating false and misleading advertisements.

Tribute to Health Team

For more than 100 years the health department of the kingdom, the provisional government, the republic and the Territory of Hawaii, in sequence, have been actively engaged in a program of regulatory controls of foods and drugs as health and economic problems. The Territory of Hawaii is grateful and proud of those dedicated clerks of the market, food and sanitary inspectors, engineers, commissioners, chemists, veterinarians, presidents, and others in the health team who have contributed toward making Hawaii one of the true health garden spots on the face of the earth!

(Continued on page 606)

COSMETICS, CHEMICALS AND CLAIMS

A FEW YEARS AGO, a dealer in essential oils, worried by recurring complaints of reactions from his perfumes and scents, decided to test the oils being used in his factory to be sure his products would cause no adverse effects. By animal experimentation, he found about a score of ingredients that he considered safe for incorporation in any formula, and then with great confidence he started marketing compounds that contained only these ingredients. The results were disappointing. As the new formulas began to cause reactions, he remembered that when two reactive chemicals are mixed together, you are apt to get a new compound differing significantly from either of the starting materials.

The tendency of separate ingredients to undergo chemical change in a final formulation is characteristic not only of essential oils, but also of many other ingredients used in cosmetics. Some of the changes are desirable and without harm. For example, we want the change that takes place when beeswax and borax combine to form an emulsifying agent for creams. But some of the changes are harmful.

Even though the perfume manufacturer forgot some of his chemistry, his motives were good. He recognized the principle that substances to be applied to the human body should be tested for safety before they are marketed. He was going in the right direction. And we all recognize that your industry, under the able leadership of Steve Mayham, Harold Goulden and Fuller Holloway, has made tremendous advances in the use of modern scientific techniques.

Over the years, some cosmetic manufacturers have failed to test their products carefully; the results have been distressing and sometimes disastrous. You know of the incidents, but just to refresh our memories, let's list some classic examples of the past few years: There was the solution for giving permanent waves without heat that killed a user because of the presence of ammonium hydrogen sulfide;

By GEORGE P. LARRICK

At the June Convention of The Toilet Goods Association, Inc., at Poland Spring, Maine, the Commissioner of Food and Drugs Emphasized the Need for Safe Cosmetics and Truthful Labeling

several hair straighteners and shampoos caused injuries because of excess alkali; a modified resin in hair lacquer burned users; a new nail base coat caused severe injuries in 1949; in 1957 a plastic press-on fingernail coating had to be recalled because of extensive injuries; a liquid cream irritated the eyes of users and had to be recalled; rapid driers for nail polish and hair contained enough carbon tetrachloride to cause harm through inhalation or skin contact; a number of shampoos damaged eyes when the shampoos dripped into them.

Each of these incidents has one thing in common. The cosmetic was not tested adequately before marketing to determine that it could be used safely. Had adequate tests been performed and, in some cases, had an adequate review of the literature been made, the firms could readily have determined that the preparations were not safe. In fact, some manufacturers investigated the new detergent ingredients that were responsible for eye injuries and widespread recalls in 1952, and decided not to put the detergents in their shampoos.

The American woman today wants a greater assurance of safety in her cosmetics. There are increasing demands for a change in the federal law which would require adequate testing of cosmetics before they are placed on the market. Bills were introduced before the Eighty-fifth Congress to require such testing.

The Department of Health, Education, and Welfare is studying these bills, but has not yet taken a position with respect to them, so we are not in a position to comment on the specific bills. However, it seems reasonable to conclude that eventually there will be legislation requiring cosmetics to be tested for safety before they are marketed.

The situation with respect to cosmetics is quite comparable with the situation that prevails in the food field. As you know, there is a growing desire for adequate testing of chemical food additives before they are marketed, and our Department has drafted proposed legislation to strengthen the federal law with respect to them. The basic principles that the Department has followed in drafting chemical-food-additives legislation are:

(1) The intended use of an additive in a food should be shown to be safe from the standpoint of long-term, as well as short-term, consumption before it is tolerated.

(2) The use of a poisonous or deleterious additive should serve a purpose beneficial to the consumer. The purposeless addition of poisons to food should not be permitted.

(3) Evidence to establish the above points should be secured by the person who wishes to promote uses of the additive and should be submitted to the government for evaluation. The proposed use should be permitted by the government only after a favorable decision by competent scientists.

(4) There should be adequate provision for appeal of an adverse government decision to the courts according to procedures that permit full consideration of complex scientific questions by scientists. New, untried appeal procedures should not be experimented with in this field of public-health protection.

(5) Any additive already in use whose safety is not generally recognized should be tested to establish its safety. There should be a reasonable period of time after the new law goes into effect to permit such testing.

We do not know whether a food-additives amendment will be passed this year, but there is such general recognition of the need for corrective legislation that we can anticipate such an amendment sooner or later.

How Control of New Cosmetics and Control of New Food Additives Differ

There is one respect in which the control of new cosmetics and the control of new food additives may have to differ materially. The Department has proposed in its food-additives bill that each new additive be tested before marketing and, on the basis of the test results, that the government determine and publish by regulation the

conditions under which it may safely be employed in food. Thus, a regulation might provide that a certain additive could be used in bakery products in a concentration not to exceed 0.1 per cent. Scientists tell us that this is a proper method of controlling most of the chemical food additives. But this procedure would not necessarily afford acceptable safeguards with respect to new cosmetic ingredients. Remember the perfume manufacturer and his attempt to solve the toxicity problem. Adequate control of cosmetic toxicity may require an evaluation of each separate formula before a valid safety decision can be reached. The procedure for doing this is already established in the present law. For 20 years we have been handling new drugs on that basis. A new-drug application refers to a given formulation intended for marketing and not to a single ingredient intended to be used in many different formulations.

This question deserves thorough study both by the government and by the industry.

Status of Coal-Tar Colors

Another subject of considerable interest these days is the status of the coal-tar colors. The law provides for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for certification of batches of these listed colors. In similar manner it provides for the listing of colors that are harmless and suitable for use in foods and in drugs.

As you know, we believe that the term "harmless" must be interpreted literally. Thus, for a color to be eligible for listing or to remain on the list it must be harmless under all possible methods of use. We found a few years ago that some of the listed food colors were not harmless. Two of them caused sickness in children when they were used in relatively high amounts in candy and popcorn for sale during the Halloween season. The laboratory studies that followed showed that two of the red colors, one orange and four yellows that had been listed for use in foods, drugs and cosmetics are not literally "harmless." We have already delisted the reds and the orange and are in process of delisting the four yellow colors. Additional long-term studies are under way on other Food, Drug, & Cosmetic colors, and we recently started preliminary studies on some of the drug and cosmetic colors. Subacute toxicity studies on D&C Reds Nos. 7, 9, 10, 19, 21, 27 and 36 and on Oranges Nos. 5 and 17 have cast some doubt upon the ability of these colors to meet the criterion of "harmless-

ness" set forth in the law. Further investigation is required before we can determine the future status of some of them.

We all recognize that some of the food colors that have been delisted and are in process of being delisted might be safe for use in food under a tolerance restriction. However, we believe the law does not give us the right to establish tolerances for the colors.

Suggestion by Coal-Tar Color Industry

To meet this situation, the coal-tar color industry has suggested an amendment that would permit us to establish safe tolerances and safe conditions for use for colors that do not meet a strict requirement of harmlessness. Our Department has not completed its study of these bills, so again I am not in a position to bring you a detailed report of our views on them. However, the Department has agreed with us that a tolerance-setting procedure would be a more rational approach to the problem.

I would like to recognize and applaud the efforts the Toilet Goods Association and Steve Mayham and Fuller Holloway have made to get industry support of, and compliance with, present law. They have worked hard to get safe cosmetics and truthful labeling. Despite their efforts we have concluded reluctantly that the cosmetic industry has not shown that it is able to protect the public adequately from extravagant claims by self-policing. There are some opportunists in your industry who cannot resist the urge to capitalize improperly on new fanciful ingredients and developments.

The opportunist makes extravagant claims about some new ingredient, even though it may not accomplish the benefits attributed to it. Then, while the government develops the evidence necessary to reach a sound decision, he rakes in the profits from his scheme. He stops either when we prove that the claims are false or when the public becomes disillusioned and turns to some other product.

We still encounter occasional cosmetics that are supposed to have miraculous properties because a little turtle oil is present. If your experience with turtles has been the same as mine—the necessity of taking them off your fish hook once in a while and chasing them out of your tomato patch—I expect you share my amazement that any woman would rely upon the oil of the turtle for cosmetic benefits. But we understand that the turtle lives to a ripe old age and this must be due to the oil in his body and so if you just smear a cream

containing the oil on your face you will get miraculous skin rejuvenation; sagging muscles will be firmed up; and the oil will bring back a fresh, youthful glow to the aging face and throat skin. I don't believe it, but that is the approach of some of the people on Madison Avenue. I have never been able to figure out what will keep the turtle oil user from getting skin as wrinkled and ugly as the turtle's.

You don't have to go back to turtle oil to find examples of wild cosmetic promotion. Within the recent past, we have encountered the use in cosmetics of chick embryo extract or so-called biostimulines, which are supposed to regenerate new cells and prevent wrinkles and sagging skin; plankton, the minute organisms of the sea, for use as a skin food, nutritive and decongestive; pigskin extract as a skin rejuvenator; roasted and powdered hair as a hair grower; horse-blood serum as a skin rejuvenator; amniotic fluid to accomplish the same benefit; shark oil to bring vitality and usefulness to dry, aging skin; and orchid pollen, which was heralded as an ingredient with no special claims. Apparently it's so good they can't tell you what it's for. We have encountered a lotion containing a placenta residue that is supposed to be good for aging skin, wrinkles, and skin rejuvenation—a truly amazing claim when you consider that the placenta ingredient is the residue left after the pharmaceutical manufacturer has extracted the valuable constituents from the placenta.

A few days ago we encountered a tranquilizer for the skin which is supposed to relieve the appearance of stress and strain due to the pace of modern living. Also, we recently have seen a great surge of promotion for that inestimable, priceless gift of the beehive—royal jelly. If you believe the advertising, royal jelly is good for anything that ails you. If you look at the prices being charged for it, it ought to be.

How Wild Claims Harm Entire Industry

Unfortunately, the originator is not the only one that gets mixed up in these wild promotional schemes. Perhaps he starts the parade but, once he begins to make headway, other firms find themselves caught in a competitive situation which they evidently believe requires that they adopt the new ingredient and the wild claims being made for it. Continued reliance on unsupportable wild claims cannot help but work to the ultimate harm of your entire industry. We urge you to find a solution to this problem. Perhaps your association will wish to develop a statement of fundamental principles for the guidance of its members. **[The End]**

By BERNARD E. CONLEY

CLOSING THE GAP IN LA

THE GROWING DEMAND for uniform legislation to require precautionary labeling of all chemical products which are not now so regulated was discussed at a legislative conference held on May 9, 1958, at the American Medical Association Headquarters, in Chicago. Speaking to government, industry and medical representatives from approximately 40 national organizations, members of the AMA Committee on Toxicology discussed the "uniform hazardous substances act" and compared it with other tentative legislation which has been proposed. A comparison of the principal features of the AMA and another model bill proposed for state and national legislature follows this article.

Attention was first focused on the general nature of the problem, as seen by the medical profession, public health officials and the public, in remarks by a pediatrics representative and by officials of the American Public Health Association and the National Safety Council. The principles which the committee employed in formulating the provisions of a model law for labeling all types of hazardous substances were next reviewed.

Label Law Principles

Briefly stated, these principles are as follows:

(1) Precautionary labeling should be applicable to all chemical products containing hazardous substances which are not now so regulated. These include packaged chemicals intended for home, commercial and industrial use, but exclude products subject to existing labeling statutes, such as drugs, economic poisons, etc. The committee's recommendations are, therefore, intended to supplement rather than to supplant existing legislation.

LABEL LEGISLATION

The Secretary, Committee on Toxicology, AMA, Urging the Need for Uniform Legislation Re Labeling of All Chemical Products Containing Hazardous Substances, Presents a Comparison of Two Model Bills—One Drafted by His Committee

(2) The same labeling standards should apply to chemicals for export to foreign countries as those for domestic consumption, thereby obviating the recurring complaint that less-than-standard products are sold to foreign purchasers.

(3) The reuse, for hazardous substances, of food and drug containers bearing their original labels or identifiable with food and drug containers by reason of shape or other characteristic should be prohibited.

(4) Strongly sensitizing chemicals, which cause allergic or inflammatory reactions in living tissues on contact, require identification and appropriate warning on the label.

(5) The term "poison" should be abandoned in view of the wide variation in existing legal limits for poison and the marked lack of agreement among scientific experts on a definition of this term and on its usefulness. Therefore, in lieu of a generally accepted definition of "poison," substances capable of causing death to any age group are dangerous chemicals, and should be so designated on the label.

(6) Label warnings should be based on the anticipated degree of danger and should use words and symbols that facilitate recognition and would be meaningful even to the illiterate.

(7) Reference standards for toxicity should be based on animal tests, which provide a consistent, and usually reliable, index of the

poisonous properties of a chemical, rather than on undefined human experience for which no measurement is provided. For purposes of legislation, a toxic (poisonous) substance may be any material which kills, within two weeks, half or more of a group of laboratory animals (rats, rabbits) in a single oral dose of 5 grams per kilogram of body weight or less or on skin contact for 24 hours in a concentration of 1 gram per kilogram or less. Comparable standards are proposed for inhalation of atmospheric concentrations of toxic gases, vapors, mists or dusts. Degrees of toxicity and other types of hazard should be reflected through the use of signal words and a single statement of principal hazards on the label.

Industry Objections

The general discussion which followed brought out the following significant comments:

Organized industrial medicine was in sympathy with the aims of the "uniform hazardous substances act" but there were objections to some of the standards employed, such as (1) omission of the term "poison" and the substitution of "toxic" which is less familiar to the public, (2) the possibility of excessive labeling because of broadening of other standards and (3) basing of the inhalation standards upon acute toxicity, without taking into account the industrial hazard of chronic exposure.

An industrial-hygiene representative agreed with the concern expressed over the numerical figures in the toxicity standards and felt that the bill did not protect the industrial worker so far as the identification of mixtures was concerned. Other industrial-medicine representatives questioned whether problems relating to industry could best be solved through legislation or by voluntary means or whether effective legislation could be arrived at by covering household and industrial products in one bill, since they were felt to represent two entirely different fields with separate problems.

It was contended that dependence should be placed on the English language to express the broad intent of such legislation and that determination of the toxicity of a product should be left to the administrator of the act. It was further expressed, by these representatives, that some manufacturers feel that information relating to the toxic hazard of the product should not be put on the label but should be made available to poison-information centers.

Committee Replies

In reply to these questions, it was brought out that the bill under discussion is directed primarily to packaged chemicals used in the home and work environment and, therefore, not intended to conflict with prevailing regulations for the shipment of industrial chemicals in large quantities.

It was also pointed out that the term "toxic" was not substituted for the term "poison," which appears in other legislative proposals; rather, the committee was disinclined to further compound the legislative conflict over the term "poison" by adding another definition of its own making. It endorses the use of the signal words "danger," "warning" and "caution" not only to express degrees of hazard, as set forth by the toxicity standard, but the other types of hazard (that is, corrosive, explosive, flammable, irritant, radioactive and sensitizer) described in the definition of "hazardous substances." It was also emphasized that the committee recommends the use of appropriate standards in conjunction with the use of these terms wherever applicable and practical. The use of precise standards for toxicity and other hazards was defended on the basis that the failure of otherwise acceptable and well-intended legislation is attributable to the lack of definite standards in the provision of its terms.

The committee held some reservation about the ability of the label-reading public to distinguish the subtle connotations of the various toxic hazards reflected by these signal words. They, therefore, recommend that consideration be given to the employment of generally accepted symbols to bridge the language barrier.

The question of whether the poisoning problem could better be solved through voluntary control was countered by a municipal health department official who referred to the impressive number of agencies which have worked on labeling programs and regulations for a considerable number of years without evident agreement. An appeal was made for understanding and an earnest attempt to reach an agreement, at least in areas where no conflict is evident. With this approach, he believed something significant would ultimately be accomplished.

The chairman, in behalf of the association and the committee, expressed to the participants appreciation for a very instructive meeting. The secretary advised that a second conference, for all segments of the chemical industry, has been scheduled for July 25 at AMA

headquarters and informed the participants that the minutes of the first conference would be available prior to the July meeting. Invitations to participate in this meeting have since been extended to over 100 organizations, including trade associations, commercial testing laboratories, chemical trade unions, and similarly interested groups.

[The End]

Comparison of Labeling Acts

CSMA Model Bill [1]

To regulate the distribution and sale of packages of hazardous substances *intended for household use.*

Section 1—This act may be cited as the *Hazardous Substances Labeling Act.*

Section 2—Definitions

(A) Department
(B) Secretary
(C) Person
(D) Hazardous substance

1. Toxic
2. Corrosive
3. Irritant
4. Flammable
5. Radioactive
6. Generates pressure through decomposition, heat, etc.

(E) "Toxic" shall apply to any substance which has the inherent capacity to produce bodily injury to man through ingestion, inhalation, or absorption through the skin.

(F) "Poison" means any toxic substance which falls within any of the following categories:

a—produces death within *48 hours* in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of *50 milligrams* or less per kilogram of body weight, when administered orally.

b—produces death within *48 hours* in half or more than half of a group of

AMA Model Bill [2]

To regulate the distribution and sale of hazardous substances for *household, commercial and industrial use.*

Section 1—This act may be cited as the *Uniform Hazardous Substances Act.*

Section 2—Definitions

(a) Department
(b) Commissioner
(c) Person
(d) Hazardous substance

1. Toxic
2. Corrosive
3. Irritant
4. *Strong sensitizer*
5. Flammable
6. Radioactive
7. Generates pressure through decomposition, heat, etc.

(e) "Toxic" shall apply to (1) any substance which:

A—produces death within *14 days* in half of more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of *5 grams* or less per kilogram of body weight, when administered orally.

B—produces death within *14 days* in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of *200 micrograms* or less per liter of gas, vapor, mist or dust.

[1] **Drafted by the Precautionary Labeling Committee, Chemical Specialties Manufacturers Association, Inc., 50 East 41st Street, New York 17, New York.**

[2] **Drafted by the Committee on Toxicology, American Medical Association, 535 North Dearborn Street, Chicago, Illinois.**

CSMA MODEL BILL	AMA MODEL BILL
10 or more laboratory white rats each weighing between 200 and 300 grams, when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of *2 milligrams* or less per liter of gas, vapor, mist or dust, *provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner.*	C—produces death within *14 days* in half or more than half of a group of 10 or more rabbits tested in a dosage of 1 gram or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.
c—produces death within *48 hours* in half or more than half of a group of 10 or more rabbits tested in a dosage of *200 milligrams* or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less.	
2. [*sic*] If available data on human experience with any substance *which in contact with any substance* in the above named dosages or concentrations indicate results different from those obtained on animals, the human data shall take precedence.	(e)(2) If *the commissioner finds that* available data on human experience with any substance in the above-named dosages or concentrations indicate results different from those obtained on animals, *he may declare such substance to be toxic or not to be toxic for the purposes of this act.*
(G) "Corrosive" means any substance which in contact with living tissue will cause *substantial destruction* of tissue by chemical action, but shall not refer to action on inanimate surfaces.	(f) "Corrosive" means any substance which in contact with living tissue will cause *destruction* of tissue by chemical action, but shall not refer to action on inanimate surfaces.
(H) "Irritant" means any substance, *not corrosive within the meaning of subsection (G) of this section, which in contact* with normal living tissue will induce a *severe* local tissue reaction.	(g) "Irritant" means any substance which *on immediate, prolonged or repeated contact* with normal living tissue will induce *substantial* local tissue reaction.
	(h) "Strong sensitizer" means any substance which, through an allergic or photodynamic process may cause an inflammatory reaction in living tissue on contact in susceptible individuals. The frequency and severity of the sensitization reaction shall determine whether a sensitizing material offers a significant potentiality for causing injury.
(I) "Flammable" shall apply to any substance which has a flashpoint of 80° F, or below, as determined by the Tagliabue open-cup tester, except that the flammability of the contents of	(i) "Flammable" shall apply to any substance which has a flashpoint of 80° F, or below, as determined by the Tagliabue open-cup tester, except that the flammability of the contents of self-

CSMA MODEL BILL	AMA MODEL BILL
self-pressurized containers shall be determined by methods generally applicable to such containers and established by *regulations issued by the Secretary.*	pressurized containers shall be determined by methods generally applicable to such containers and established by *regulations issued by the Commissioner. This term shall also include "extremely flammable" substances which are flammable at or below 20° F in the presence of air, oxygen or other suitable oxidizing substance.*
(J) *"Radioactive" shall apply to any substance which, as a result of disintegration of unstable atomic nuclei, emits energy.*	(j) *"Radioactive" shall apply to all radiations capable of producing ions directly or indirectly in their passage through matter, including (but not limited to) electromagnetic radiations, such as X rays, and gamma rays, and particulate radiations, such as alpha particles, etc.*
(K) "Label" means a display of written, printed, or graphic matter upon the immediate container of any substance, and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such substance, or is easily legible through the outside container or wrapper.	(k) "Label" means a display of written, printed or graphic matter upon *or attached* to the immediate package or container of any substance, and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package *or bulk container* of such substance, or is easily legible through the outside container or wrapper. *This term shall also include the term "labeling," which embraces all labels and other written, printed or graphic matter upon or accompanying the hazardous substances or any of its containers to which reference is made on the label or in the literature accompanying the hazardous substance.*
(L) The term "immediate container" does not include package liners.	(l) The term "immediate container" does not include package liners.
(M) "Misbranded package" means any retail package of a hazardous substance, intended for household use, which fails to bear a label	(m) "Misbranded package" means any retail package *or bulk container* of a hazardous substance which fails to bear a label
(1) which states conspicuously	(1) which states conspicuously
(a) the name and place of business of the manufacturer, packer, or distributor;	(A) the name and place of business of the manufacturer, packer, or distributor;
(b) the common or usual name, *or* the chemical name (if there be no com-	(B) the common or usual name, *and* the chemical name or the *recognized*

CSMA MODEL BILL	AMA MODEL BILL
mon or usual name) or the *recognized generic name* (not trade name) of the hazardous substance *or* of each component which contributes substantially to its hazard;	*nonprotected name* (not trade name only) of the hazardous substance of each component which contributes substantially to its hazard;
(c) one of the following signal words: "Danger," "Warning," or "Caution";	(C) one of the following signal words: "DANGER," "WARNING" or "CAUTION," *to indicate the degree of hazard;*
(d) when necessary an affirmative statement of the principal hazard or hazards such as "flammable," "vapor harmful," "causes burns," "absorbed through skin," or similar wording descriptive of the hazard;	(D) *the signal word "DANGER" for substances which are extremely flammable, highly corrosive, explosive or radioactive, and for substances which because of toxicity present comparably serious hazards; defined in terms of acute lethal dose by mouth, skin or other body surfaces, the range is up to one gram per kilogram of body weight;* (E) *the signal word "WARNING" for less toxic substances whose acute lethal dosage range may be between one gram and five grams per kilogram;* (F) *the signal word "CAUTION" only for the least hazardous substances; defined in terms of acute lethal dose, it may include those substantances with fatal effects in amounts greater than five grams per kilogram.* (G) an affirmative statement of the principal hazard or hazards, *when required by the commissioner,* such as "flammable," "vapor harmful," "causes burns," "absorbed through skin," *or* similar wording descriptive of the hazard;
(e) precautionary measures describing the action to be followed or avoided;	(H) precautionary measures describing the action to be followed or avoided;
(f) instructions, when necessary, for the first-aid treatment in case of contact or exposure, if the substance is hazardous through contact or exposure;	(I) instructions, when necessary, for the first-aid treatment in case of contact or exposure, if the substance is hazardous through contact or exposure;
(g) *the word "Poison" for any substance which is defined as poisonous by subsection (F);*	
(h) instructions for handling and storage of packages which require special care in handling or storage;	(J) instructions for handling and storage of packages which require special care in handling or storage;
(i) the statement "keep out of the reach of children," or its practical equivalent; and	(K) the statement "keep out of the reach of children," or its practical equivalent *on retail packages offered for household use,* and

CSMA MODEL BILL

(2) on which any statements required under clause (1) of this subsection are located prominently and are in English in legible type in contrast by typography, layout, or color with other printed matter on the label: PROVIDED, That the *secretary* shall, by regulations, provide for minimum information which shall appear on the labels for small packages, which labels need not include all of the information required by this subsection: PROVIDED FURTHER, That the *secretary* may provide for less than the foregoing statement of the hazard of precautionary measures for labels of hazardous substances presenting only minor hazards; and the term "misbranded package" shall not apply to packages of economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to packages of substances subject to the Federal Food, Drug, and Cosmetic Act, or to packages of substances intended for use in agriculture, horticulture, industrial, or related uses.

Section 3—Prohibited Acts

No person shall sell, offer for sale, distribute or transport for sale within the state in a package or container intended for general home and household use any misbranded package of a hazardous substance.

AMA MODEL BILL

(2) on which any statements required under clause (1) of this subsection are located prominently and are in English in legible type in contrast by typography, layout, or color with other printed matter on the label: Provided, That the *commissioner* shall, by regulations, provide for minimum information which shall appear on the labels for small packages, which labels need not include all of the information required by this subsection: Provided further, That the *commissioner* may provide for less than the foregoing statement of the hazard or precautionary measures for labels of hazardous substances presenting only minor hazards; and the term "misbranded package" shall not apply to packages of economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to packages of foods and drugs subject to the Federal Food, Drug, and Cosmetic Act, or to packages of substances intended for use in agriculture horticulture, or related arts or sciences.

Section 3—Prohibited Acts

The following acts and the causing thereof are hereby prohibited.

(a) The sale or delivery for sale of any misbranded package of a hazardous substance.

(b) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the label of, or the doing of any other act with respect to a hazardous substance, if such act is done while the substance is held for sale and which results in the hazardous substance's being in a misbranded package.

(c) The receipt of any misbranded package of a hazardous substance and the delivery or proffered delivery thereof for pay or otherwise.

(d) The giving of a guaranty or undertaking referred to in Section 4(b)(2) which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the

CSMA MODEL BILL

Section 4—Regulations and Hearings

The authority to enforce this act is vested in the secretary. The secretary shall from time to time for the efficient enforcement of this Act promulgate regulations after public hearing following due notice at least ten days in advance of the hearing to interested persons.

AMA MODEL BILL

same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance.

(e) The refusal to permit entry or inspection as authorized by Section 8(b).

(f) A *re-use* of food, drug or cosmetic containers still bearing original labels or identifiable as such by characteristic shape, impression or closures as containers for hazardous substances is prohibited.

Section 4—Penalties

(a) Any person who violates any of the provisions of Section 3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than $500, but if the violation results from willful disregard of the provisions of this act, the penalty shall be imprisonment for not more than 1 year, or a fine of not more than $3,000, or both such imprisonment and fine.

(b) No person shall be subject to the penalties of subsection (a) of this section, (1) for having violated Section 3 (c), if the receipt, delivery, or proffered delivery of the hazardous substance was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the commissioner, the name and address of the person from whom he purchased or received such hazardous substance, and copies of all documents, if any there be, pertaining to the delivery of the hazardous substance to him; or (2) for having violated Section 3(a), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance, to the effect that the hazardous substance is not in misbranded packages within the meaning of that term in this act; or (3) for having violated subsection (a) or (c) of Section

CSMA MODEL BILL

Section 5—Seizures

Any hazardous substance that is in a misbranded package when introduced into or while in intrastate commerce within this state for sale within the state shall be liable to be proceeded against on libel of information and condemned in any court within this state having jurisdiction over such an action. Any hazardous substance condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid to the state treasurer, but such hazardous substance shall not be sold under such decree contrary to the provisions of this act or the laws of the jurisdiction in which sold provided that, upon the payment of costs of the proceeding and the execution and delivery of a good and sufficient bond conditioned that such hazardous substance shall not be sold or disposed of contrary to the provisions of this act, the court may direct that such hazardous substance be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this act by relabeling or reprocessing, as the case may be.

AMA MODEL BILL

3 in respect of any hazardous substance shipped or delivered for shipment for export to any foreign country, in a package marked for export and branded in accordance with the specifications of the foreign purchaser and in accordance with the laws of the foreign country.

Section 5—Seizures

(a) Any hazardous substance that is in a misbranded package shall be liable to be proceeded against on libel of information and condemned in any county court of the state within the jurisdiction of which the hazardous substance is found. *This section shall apply to a hazardous substance intended for export to any foreign country.*

(b) Such hazardous substance shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty, except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the state or the claimant reasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any county selected by the applicant where one of such proceedings is pending or (2) a county agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the state or the claimant may apply to the court of one such jurisdiction, and such court (after giving the other party, the claimant, or the state's attorney for such county, reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a county of reasonable proximity to

CSMA MODEL BILL

When a decree of condemnation is entered against the hazardous substance, court costs and fees, and storage and other proper expenses shall be awarded against the person, if any, intervening as claimant of the hazardous substance.

AMA MODEL BILL

the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Any hazardous substance condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the treasury of the state; but such hazardous substance shall not be sold under such decree contrary to the provisions of this act: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such hazardous substance shall not be sold or disposed of contrary to the provisions of this act, the court may by order direct that such hazardous substance be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this act under the supervision of an officer or employee duly designated by the commissioner, and the expenses of such supervision shall be paid by the person obtaining release of the hazardous subsance under bond.

(d) When a decree of condemnation is entered against the hazardous substance, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the hazardous substance.

(e) In the case of removal for trial of any case as provided by subsection (b)—(1) the clerk of the court from which removal is made shall promptly transmit to the court in which the case

CSMA MODEL BILL

AMA MODEL BILL

is to be tried all records in the case necessary in order that such court may exercise jurisdiction; (2) the court to which such case is removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

Section 6—Hearing Before Report of Criminal Violation

Before any violation of this act is reported to the district attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views to the secretary, either orally or in writing, with regard to such contemplated proceeding. *Nothing in this act shall be construed as requiring the secretary to report for prosecution or for the institution of libel proceedings minor violations of the act whenever he believes that the public interest will be best served by a suitable notice of warning in writing.*

Section 6—Hearing Before Report of Criminal Violation

Before any violation of this act is reported by the commissioner to any state's attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

Section 7—Penalties

Any person violating the provisions of this act shall be guilty of a misdemeanor and shall be fined not more than $..... or imprisoned for not more than ..... months, or both.

Section 7—Regulations and Hearings

(a) The authority to promulgate regulations for the efficient enforcement of this act, except as otherwise provided in this section, is hereby vested in the commissioner.

Section 8—Examinations and Investigations

(a) The commissioner is authorized to conduct examinations, inspections and investigations for the purposes of this act through officers and employees of the department or through any health officer or employee of the state.

(b) For purposes of enforcement of this act, officers or employees duly designated by the commissioner, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which hazardous substances are held, or to enter any vehicle being used to transport or hold such hazardous substances and (2) to inspect and sample, at reasonable times and within reasonable limits and in a reasonable manner,

AMA MODEL BILL

finished hazardous substances in retail packages and labeling thereon in such factory, warehouse, establishment, or vehicle. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Section 9—Records of Shipment

For the purpose of enforcing the provisions of this act, carriers and persons receiving hazardous substances or holding such hazardous substances so received, shall, upon the request of an officer or employee duly designated by the commissioner, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement of any such hazardous substance, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to any copying of any record so requested when such request is accompanied by a statement in writing specifying the nature or kind of such hazardous substance to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

Section 10—Publicity

(a) The commissioner may cause to be published from time to time reports summarizing any judgments, decrees, or court orders which have been rendered under this act, including the nature of the charge and the disposition thereof.

(b) The commissioner may also cause to be disseminated information regarding hazardous substances in situations involving, in the opinion of the commissioner, imminent danger to health. Nothing in this section shall be construed to prohibit the commissioner from collecting, reporting, and illus-

CSMA MODEL BILL	AMA MODEL BILL
	trating the results of the investigations of the department.
	Section 11—Separability Clause
	If any provision of this act is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the act and the applicability thereof to other persons and circumstances shall not be affected thereby.
Section 8—Time of Taking Effect	Section 12—Time of Taking Effect
This act shall take effect January 1, 19 .	This act shall take effect upon the date of its enactment, but no penalty or condemnation shall be enforced for any violation of this act occurring within six months after the date of its enactment.

Text of AMA Model Bill

"AN ACT

"To regulate the distribution and sale of hazardous substances for household, commercial, and industrial use.

"Be it enacted by the Legislature of the State of .

"SHORT TITLE

"SECTION 1. This Act may be cited as the 'Uniform Hazardous Substances Act'.

"DEFINITIONS

"SEC. 2. For the purposes of this Act—

"(a) The term 'Department' means the Department of .

"(b) The term 'Commissioner' means the Commissioner of the Department of .

"(c) The term 'person' includes an individual, partnership, corporation, and association.

"(d) The term 'hazardous substance' means any substance or mixture of substances which is (1) toxic, (2) corrosive, (3) an irritant, (4) strong sensitizer, (5) flammable, (6) radioactive, or which (7) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or illness during any customary or reasonably anticipated handling or use.

"(e) The term 'toxic' shall apply to (1) any substance which (A) produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of five grams or less per kilogram of body weight, when orally administered; or (B) produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of 200 micrograms or less per liter of gas vapor, mist or dust; or (C) produces death within four-

teen days in half or more than half of a group of ten or more rabbits tested in a dosage of one gram or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less. (2) If the Commissioner finds that available data on human experience with any substance in the above named dosages or concentrations indicate results different from those obtained on animals, he may declare such substance to be toxic or not to be toxic for the purposes of this Act.

"(f) The term 'corrosive' means any substance which in contact with living tissue will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

"(g) The term 'irritant' means any substance which on immediate, prolonged or repeated contact with normal living tissue will induce substantial local tissue reaction.

"(h) The term 'strong sensitizer' means any substance which, through an allergic or photodynamic process may cause an inflammatory reaction in living tissue on contact in susceptible individuals. The frequency and severity of the sensitization reaction shall determine whether a sensitizing material offers a significant potentiality for causing injury.

"(i) The term 'flammable' shall apply to any substance which has a flash-point of eighty degrees Fahrenheit, or below, as determined by the Tagliabue open cup tester, except that the flammability of the contents of self-pressurized containers shall be determined by methods generally applicable to such containers and established by regulations issued by the Commissioner. This term shall also include 'extremely flammable' substances which are flammable at or below twenty degrees Fahrenheit in the presence of air, oxygen or other suitable oxidizing substance.

"(j) The term 'radioactive' shall apply to all radiations capable of producing ions directly or indirectly in their passage through matter, including (but not limited to) electromagnetic radiations, such as x-rays, and gamma rays, and particulate radiations, such as alpha particles, beta particles, electrons, protons and neutrons.

"(k) The term 'label' means a display or written, printed or graphic matter upon or attached to the immediate package or container of any substance; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package or bulk container of such substance, or is easily legible through the outside container or wrapper. This term shall also include the term 'labeling' which embraces all labels and other written, printed or graphic matter upon or accompanying the hazardous substances or any of its containers to which reference is made on the label or in the literature accompanying the hazardous substance.

"(l) The term 'immediate container' does not include package liners.

"(m) The term 'misbranded package' means any retail package or bulk container of a hazardous substance which fails to bear a label (1) which states conspicuously (A) the name and place of business of the manufacturer, packer, or distributor; (B) the common or usual name, and the chemical name or the recognized non-protected name (not trade name only) of the hazardous substance of each component which contributes substantially to its hazard; (C) one of the following signal words: 'DANGER', 'WARNING' or 'CAUTION' to indicate the degree of hazard; (D) the signal word 'DANGER' for substances which are extremely flammable, highly corrosive, explosive or radioactive, and

for substances which because of their toxicity present comparably serious hazards; defined in terms of acute lethal dose by mouth, skin or other body surfaces, the range is up to one gram per kilogram body weight; (E) the signal word 'WARNING' for less toxic substances whose acute lethal dosage range may be between one gram to five grams per kilogram; (F) the signal word 'CAUTION' only for the least hazardous substances; defined in terms of acute lethal dose, it may include those substances with fatal effects in amounts greater than five grams per kilogram; (G) an affirmative statement of the principal hazard or hazards, when required by the Commissioner, such as 'Flammable', 'Vapor Harmful', 'Causes Burns', 'Absorbed Through Skin', or similar wording descriptive of the hazard; (H) precautionary measures describing the action to be followed or avoided; (I) instructions, when necessary, for the first-aid treatment in case of contact or exposure, if the substance is hazardous through contact or exposure; (J) instructions for handling and storage of packages which require special care in handling or storage; and (K) the statement 'Keep out of the reach of children', or its practical equivalent on retail packages offered for household use, and (2) on which any statements required under clause (1) of this subsection are located prominently and are in English in legible type in contrast by typography, layout, or color with other printed matter on the label: Provided, That the Commissioner shall, by regulations, provide for minimum information which shall appear on the labels for small packages, which labels need not include all of the information required by this subsection: Provided further, That the Commissioner may provide for less than the foregoing statement of the hazard or precautionary measures for labels of hazardous substances presenting only minor hazards; and the term 'misbranded package' shall not apply to packages of economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act, to packages of foods and drugs subject to the Federal Food, Drug, and Cosmetic Act, or to packages of substances intended for use in agriculture, horticulture, or related arts or sciences.

"PROHIBITED ACTS

"SEC. 3. The following acts and the causing thereof are hereby prohibited.

"(a) The sale or delivery for sale of any misbranded package of a hazardous substance.

"(b) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the label of, or the doing of any other act with respect to a hazardous substance, if such act is done while the substance is held for sale and which results in the hazardous substance being in a misbranded package.

"(c) The receipt of any misbranded package of a hazardous substance and the delivery or proffered delivery thereof for pay or otherwise.

"(d) The giving of a guaranty or undertaking referred to in section 4(b)(2) which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance.

"(e) The refusal to permit entry or inspection as authorized by section 8(b).

"(f) A *re-use* of food, drug or cosmetic containers still bearing original labels or identifiable as such by characteristic shape, impression or closures as containers for hazardous substances is prohibited.

"PENALTIES

"SEC. 4. (a) Any person who violates any of the provisions of section 3 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine

of not more than $500, but if the violation results from willful disregard of the provisions of this Act, the penalty shall be imprisonment for not more than one year, or a fine of not more than $3,000, or both such imprisonment and fine.

"(b) No person shall be subject to the penalties of subsection (a) of this section, (1) for having violated section 3(c), if the receipt, delivery, or proffered delivery of the hazardous substance was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Commissioner, the name and address of the person from whom he purchased or received such hazardous substance, and copies of all documents, if any there be, pertaining to the delivery of the hazardous substance to him; or (2) for having violated section 3(a), if he establishes a guaranty or undertaking signed by, and contained the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance, to the effect that the hazardous substance is not in misbranded packages within the meaning of that term in this Act; or (3) for having violated subsection (a) or (c) of section 3 in respect of any hazardous substance shipped or delivered for shipment for export to any foreign country, in a package marked for export and branded in accordance with the specifications of the foreign purchaser and in accordance with the laws of the foreign country.

"SEIZURES

"SEC. 5. (a) Any hazardous substance that is in a misbranded package shall be liable to be proceeded against on libel of information and condemned in any county court of the State of within the jurisdiction of which the hazardous substance is found: This section shall apply to a hazardous substance intended for export to any foreign country.

"(b) Such hazardous substance shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the State of or the claimant reasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any county selected by the applicant where one of such proceedings is pending; or (2) a county agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the State of or the claimant may apply to the court of one such jurisdiction, and such court (after giving the other party, the claimant, or the State's Attorney for such county, reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a county of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

"(c) Any hazardous substance condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the State of : but such hazardous substance shall not be sold under

such decree contrary to the provisions of this Act: Provided, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such hazardous substance shall not be sold or disposed of contrary to the provisions of this Act, the court may by order direct that such hazardous substance be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Commissioner, and the expenses of such supervision shall be paid by the person obtaining release of the hazardous substance under bond.

"(d) When a decree of condemnation is entered against the hazardous substance, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the hazardous substance.

"(e) In the case of removal for trial of any case as provided by subsection (b)—

"(1) the clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction;

"(2) the court to which such case is removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

"HEARING BEFORE REPORT OF CRIMINAL VIOLATION

"SEC. 6. Before any violation of this Act is reported by the Commissioner to any State's Attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

"REGULATIONS AND HEARINGS

"SEC. 7. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Commissioner.

"EXAMINATIONS AND INVESTIGATIONS

"SEC. 8. (a) The Commissioner is authorized to conduct examinations, inspections, and investigations for the purposes of this Act through officers and employees of the Department or through any health officer or employee of the State of .

"(b) For purposes of enforcement of this Act, officers or employees duly designated by the Commissioner, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which hazardous substances are held, or to enter any vehicle being used to transport or hold such hazardous substances; and (2) to inspect and sample, at reasonable times and within reasonable limits and in a reasonable manner, finished hazardous substances in retail packages and labeling thereon in such factory, warehouse, establishment, or vehicle. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

"RECORDS OF SHIPMENT

"SEC. 9. For the purpose of enforcing the provisions of this Act, carriers and persons receiving hazardous substances or holding such hazardous sub-

stances so received, shall, upon the request of an officer or employee duly designated by the Commissioner, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement of any such hazardous substance, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to any copying of any record so requested when such request is accompanied by a statement in writing specifying the nature or kind of such hazardous substance to which such request relates: Provided, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.

"PUBLICITY

"SEC. 10. (a) The Commissioner may cause to be published from time to time reports summarizing any judgments, decrees, or court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

"(b) The Commissioner may also cause to be disseminated information regarding hazardous substances in situations involving, in the opinion of the Commissioner, imminent danger to health. Nothing in this section shall be construed to prohibit the Commissioner from collecting, reporting, and illustrating the results of the investigations of the Department.

"SEPARABILITY CLAUSE

"SEC. 11. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

"TIME OF TAKING EFFECT

"SEC. 12. This Act shall take effect upon the date of its enactment, but no penalty or condemnation shall be enforced for any violation of this Act occurring within six months after the date of its enactment."

• FOODS—BROKERAGE •

Bakery products . . . A firm engaged in the sale of bakery products is charged with favoring some customers with illegal brokerage payments. (Released September 2, 1958.)

Food products . . . A company selling food products and that company's subsidiary are charged with making illegal brokerage payments to a favored buyer of the subsidiary's Mexican-style food products. The buyer is charged with violating the law by accepting the payments. The subsidiary, which is controlled by the food-products company through 51 per cent stock ownership, distributes the major portion of the specialty items through brokers who are paid a 5 per cent commission, but sells directly to the buyer in question, the complaint states. Alleging violation of Section 2(c) of the Robinson-Patman Amendment to the Clayton Act, the complaint charges that during and since 1956 the subsidiary has granted the buyer the 5 per cent brokerage fee on these direct sales. (Released September 12, 1958.)—CCH TRADE REGULATION REPORTS ¶ 27,405; 27,414.

CHRISTOPHER

COMMENTS

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Practitioner.—A Food and Drug Administration official has expressed the opinion that a prescription written by a foreign physician for a patient in this country has no legal status. The term "practitioner licensed by law" means a practitioner licensed by state law in the United States. A separate problem arises when the prescription of a practitioner in one state is filled by a drugstore of another state. The FDA takes the position that, ordinarily, no public interest would be served by raising a question as to the technical legality of this procedure.[1]

Judge and Prosecutor.—An important administrative law ruling is concerned in a case involving a mail fraud order by the Postmaster of the City of New York.[2] The postmaster had issued a "fraud order" denying plaintiffs the use of the mails for the distribution of its advertisements. The plaintiffs had sought an injunction against the postmaster and, on appeal, they raised for the first time the objection that the "judge" and "prosecutor" in the agency are in a superior-subordinate relationship. The United States Court of Appeals for the Second Circuit upheld the objection, saying that such an arrangement violates the Administrative Procedure Act.

First, the court stated that it would be contrary to the purpose of the act if the General Counsel prepared the complaint and the Assistant Counsel made the final decision. The subordinate would thus be passing on the charges made by his superior.

Second—and this is the situation here—the act also prohibits the subordinate of the "judge" from being the "prosecutor."

The court held:

[1] CCH Food Drug Cosmetic Law Reports ¶ 7439.

[2] *Columbia Research Corporation et al. v. Schaffer*, CCH Food Drug Cosmetic Law Reports ¶ 7440 (CA-2, 1958).

It appears to us reasonable to suppose that the prosecutor will be disposed to select such cases as he believes will meet with his superior's approval, and that his discretion may be exercised otherwise than if each was responsible to the Postmaster only by a separate chain of authority.

The court admitted that, in the end, in such administrative matters, there has to be a fusion of prosecutor and judge. But it is important, the court stated, that this fusion be reserved to the highest level of authority—the agency itself and its members.

The decision does not hold that there cannot be such a fusion at the lower levels, but rather that the act does not allow it. However, even if the act does permit the fusion to take place at the lower levels, the court stated, the public must be so informed by a published regulation spelling out the exact relationship. There was no such published regulation here.

PUBLIC HEALTH SERVICE REPORTS ON RADIOACTIVITY IN MILK

The United States Public Health Service announced on September 19 that its latest tests for the presence of radioactivity in milk from nine locations in the United States have shown amounts well within the permissible levels recommended by the National Committee on Radiation Protection and Measurement. The report, which covers the months of May, June, and July, 1958, brings up to date the findings of a study initiated by the service in the spring of 1957. A report on the first year's findings was issued last May 25.

Composite milk samples collected through the cooperation of state and municipal health agencies, state departments of agriculture and the dairy industry were analyzed by the service to measure amounts of specific radioisotopes, including Strontium 90. Levels of Strontium 90 in the May samples were found to range, in the various milksheds, from 3.3 to 10.0 micromicrocuries per liter as compared to the permissible limit of 80.0 uuc/liter (a curie is a measure of radioactivity equivalent to that produced by one gram of radium; a mircromicrocurie is one millionth of a millionth of a curie). The yearly average for the period ending in May, 1958, for Strontium 90 ranged from 4.1 to 9.4 uuc/liter. Levels in the June samples were found to range from 2.2 to 15.6 micromicrocuries per liter. The yearly average for the period ending last June ranged from 4.2 to 9.6 uuc/liter. In the July samples, the levels of Strontium 90 were found to range from 3.3 to 18.7 micromicrocuries per liter. The yearly average for the period ending in July, 1958, ranged from 4.2 to 10.2 uuc/liter.

During June and July, the network was expanded from five sampling stations to nine. The four new stations reporting for the first time are on the milksheds of Atlanta, Georgia; Austin, Texas; Fargo, North Dakota; and Chicago, Illinois. An additional sampling point is being established on the milkshed of Spokane, Washington.

The Scientists' Forum

Edited by BERNARD L. OSER

Director, Food and Drug Research Laboratories, Inc.

Editor's Comment: The following address was presented by Henry F. Smyth, Jr., of the Mellon Institute, Pittsburgh, Pennsylvania, on May 28, 1958, at the eighteenth annual meeting of the Institute of Food Technologists, held at Chicago. It was a part of a panel session on "Important Current Aspects of Food Additives." Published in the August, 1958 issue of *Food Technology*, it is copyrighted by that journal and the institute, and is reprinted with their permission.

Safety-Evaluation Procedures and Interpretations

This spring, under some old apple trees, I found what I took to be a fungus, growing rather abundantly. It resembled nothing I had ever seen before nor anything I would want to eat, but it seemed to my untrained eye to match a picture of the morel in an old *National Geographic Magazine*. The caption said it is an epicure's delight, safe to eat when in good condition. My wife recalled an essay by Louis Bromfield, describing the ecstatic thrill of finding six morels, and I had 24, if they really were morels. I harvested them and gave them to my secretary. She relied upon my identification, of which I myself was uncertain, and reported them to be delightful. A second crop of 12 I tried on a colleague, who likewise survived in a state of bliss. The consistent results of this limited human experiment on safety and consumer acceptance convinced me. My wife and I ate the third crop ourselves, regretting only that five sixths of the total yield had been devoted to the evaluation of safety. An industrial firm which spent five sixths of its potential profits on evaluation of safety would not long remain in business, but my resources can stand the strain for a luxury item like the morel. Furthermore, there may be a crop next year, and safety has now been established.

What I have to say about safety evaluation applies with equal force to intentional additives used to improve the character of food and to incidental residues which may remain in food from the use of compounds in production, processing and packaging. The reason for material being present in food has no bearing on whether or not it is safe. The amount present has great bearing on safety.

It seems to me there is much loose talking and thinking on the subject of amounts. We shouldn't talk in quantitative units unless we have a tactual or operational concept of their magnitudes. How do you visualize one part per million? It is one drop (0.06 ml.) well mixed with 16 gallons, or 80 fifths. This makes a very dry martini indeed. If the perfect host had served a fifth of gin as these dry martinis every day of the Christian era, more than a quarter of his fifth of Vermouth would remain unused today. A tenth of a part per million is the thickness of a strip of cellophane in the height of the Washington monument. A part per billion is of the order of one drop in a tank car. We talk in terms of these quantities of incidental residue in foods, we must seriously question the effects upon health of their presence, and we must devise analytical methods to measure them.

Increasingly, recognition is being accorded to the fact that every action of an additive grows less as the intake falls. At some low intake of any additive, no informed person could attach public-health significance to applications. There is no sound reason to regulate applications which produce extremely low intakes. They are inconsequential, insignificant or ignorable. Visualization of the tactual definitions which I just gave for certain low levels should be convincing on this point. Who can develop concern for one drop of any probable residue in a tank car, or of several drops? At what level does concern become justifiable? This has not yet been clarified, and it will probably be different for every class of additives.

The Food Protection Committee [1] defines safety as "the practical certainty that injury will not result from use of a substance in a proposed quantity and manner." There are two very important points in this definition. Conclusion that the use of an additive is safe does not require absolute certainty that no injury can result; it requires only a practical certainty. Some undefined degree of uncertainty is compatible with the conclusion that safety has been shown. Further-

[1] Food Protection Committee, *Principles and Procedures for Evaluating the Safety of Chemical Additives in Foods* (Washington, D. C., Food and Nutrition Board, National Research Council, November, 1954).

more, it is a particular use of an additive in a particular food at a particular level which is shown to be safe; it is not the additive itself which is safe under every foreseeable condition of use.

Currently Used Technic.—Due to precedent and administrative practices, the evaluation of safety of applications of chemicals to food technology in the United States, and increasingly in the rest of the world, now usually rests on a rather standardized experimental regimen,[2] which has developed out of the 1942 work of Morris, Nelson and Calvery.[3] I see no point in dwelling upon the details of this well-known program. In outline, several concentrations of the additive are fed in the diet to groups of rats for two years. One of them must produce no discernible difference from cases where rats received none. One of them, or a higher concentration fed for a shorter time, should produce an effect sufficient to allow determination of the nature of injury from an excess. Smaller groups of dogs, or some other nonrodents, are fed more than one concentration for one year. One of these concentrations must result in no discernible difference from cases where dogs received none. From these studies there is deduced a "no-effect" level of the additive for the more sensitive of the two species. It is desirable to determine the metabolic path followed in each of the two species and in humans. If the path in only one of the species is like that of the human, than the "no-effect" level in the human is likely to be closer to the "no-effect" level in that species rather than to the more sensitive of the two species.

There is another way in which uses of a very limited number of additives have been shown to be safe. It may be loosely termed "the metabolic approach." The additive may pass through the digestive tract unabsorbed and be completely recoverable from the feces. It may be transformed by digestive enzymes or bacteria in the digestive tract into a compound known to be harmless. It may be a material which is normally present in some foods, and its use as an additive may not materially increase the total consumption. It may be metabolically closely similar to some unusual component of the diet. When any of these facts can be shown to be true, use of the additive is a priori

[2] A. J. Lehman, and others, "Procedures for the Appraisal of the Toxicity of Chemicals in Foods, Drugs and Cosmetics," 10 *Food Drug Cosmetic Law Journal* 679-748 (October, 1955).

[3] M. J. Morris, A. A. Nelson, and H. O. Calvery, "Observations on the Chronic Toxicities of Propylene Glycol, Ethylene Glycol, Diethylene Glycol, Ethylene Glycol Monoethyl Ether and Diethylene Glycol Monoethyl Ether," 74 *Journal of Pharmacology* 266-273 (1942).

safe. They are not true of very many useful additives. Happily, proof of any one of these facts is possible in a positive sense, leaving no room for doubts about the adequate sensitivity of experimental methods.

There are a number of ways in which use of a particular additive may be shown to be unsafe. At a level reasonably close to that of its proposed use, the additive may exert a marked hormone-like physiological effect, it may inhibit some enzyme system which is important in metabolism, it may be stored in the body or it may cause a specific irreversible pathological change. These actions also are demonstrable in a positive sense. When they exist, there is little room for argument. The proposed use of the additive is unsafe, although one may be misled by an experimental artifact, such as the chance reaction of one or two of a large group of animals, or an unrecognized special sensitivity of the species used for study.

Safety Factor.—Having obtained agreement that we have defined the "no-effect" level of an additive fed to experimental animals, we proceed to predict the "safe level" of the additive for the human diet. We divide by a safety factor which combines our ignorance with our lack of confidence in the accuracy of the "no-effect" level we have so laboriously defined during a three-year period.

There are several components of the safety factor. We concede that humans may be ten times as sensitive as our experimental animals. We grant that the most sensitive human may be ten times as sensitive as the average human.[4] We increase the safety factor by an undefined amount when an excess of the additive may cause an alarming type of injury or when it will be in a universally eaten major item of the diet or in an item eaten by a presumed particularly sensitive segment of the population. Furthermore, we reduce the safety factor by an undefined amount when favorable human experience has reduced the uncertainty about species differences or when the necessity to use the additive is great.

These components of the safety factor are not added together; they are multiplied. Sometimes we end by concluding that there is a practical certainty that humans will not be injured by a thousandth or less of the intake which produced no detected harm in our experimental animals.

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[4] 20 *Federal Register* 1493 (March 11, 1955).

After estimating in this conservative fashion the "safe level" of the additive in the human diet, we examine the proposed uses. The amount of the same or similarly acting materials which humans may receive in other ways is added to the amount which may be received from the proposed use. If the sum is less than the estimated "safe level," we conclude that the use is safe. Even this does not necessarily make it legal. The purpose of the additive and the necessity for its use must be considered to establish legality.

It seems to me beyond question that our current procedures adequately protect public health from excessive consumption of additives in the diet. On the other hand, it seems to me that these procedures may unnecessarily hamper the efforts of food technology to produce and distribute an increasingly attractive, varied and sanitary diet. Possibly, the study of additives accepted as safe since the dawn of history could determine whether the current standards for safety evaluation are necessary or are timidly over-conservative.

Shortcomings.—The customary program for safety evaluation has the advantage of being well-defined. One has no doubts about the experimental work which is required. No great ingenuity nor any profound knowledge of physiology or of pharmacology is called for, although constant meticulous attention to detail is required to obtain dependable results. The work may serve its administrative purpose without revealing the true way in which an excess of the additive can injure. Although sound planning allows the one-year dog feeding to be completed simultaneously with the two-year rat study, almost another year is required to complete the study of micropathology and the analysis of the findings. Three years is a long time to withhold technical application of a promising additive.

The greater number of additives can neither be shown safe by the metabolic approach nor clearly unsafe because of the positive evidences of serious effects which I have mentioned. One is usually compelled to rely upon the conventional chronic feeding study. Barnes and Denz [8] have discussed this study at some length.

The two-year feeding period approximates the natural life span of the rat. Reliance upon its results has caused no injury to public health, but I believe only because an inordinately large factor is applied to estimate the intake safe for humans. It is a specious argu-

[8] J. N. Barnes and F. A. Denz, "Experimental Methods Used in Determining Chronic Toxicity," 6 *Pharmacological Reviews* 191-242 (1954).

ment that feeding for the life of the rat is equivalent to feeding for the life of man. Wide acceptance today demonstrates that belief in magic symbolism is not dead. It is true that the rat receives the additive throughout every stage of its physiological development, maturity and senescence after weaning, just as the human will if the additive is put into use. However, the rat passes through these stages 35 times as rapidly as does the human. What esoteric mechanism causes the rat to be injured 35 times as rapidly as the human would be? If the lifetime of one species is equivalent to that of another, why be hampered by the two-year period required with rats? Why not rely upon the daphnia with its life span of a few days, its diet and metabolism not unlike man's? [6]

A more basic objection to the chronic feeding study is that it is the logically impossible effort to prove a negative. By increasingly sensitive methods we are trying to measure threshold effects, and once we succeed in measuring them we have proved there is an effect at that intake level, but we can never prove there is no effect at the next lower level. Every possible measurement can detect effects at some limiting sensitivity, but cannot prove an effect is absent at an intensity below the sensitivity. No possible set of direct observations can ever define a true "no effect" level. Frazer's discussion of safety evaluation [7] avoids this trap by basing the acceptable dietary level upon an effective dosage which can be determined experimentally, not upon the indeterminable highest ineffective level as we now do.

Other sciences are faced with the problem of estimating the ordinate at which a variable assumes some infinitesimal value approximating zero. They apply the concept of limits. They make measurements in the range where the variable is finite, where their technics allow it to be estimated with the desired accuracy. Having deduced the regular relationship between the ordinate and the value of the variable, they extrapolate to zero. In the language of pharmacology, they extrapolate the dosage-response curve to zero effect. Only toxicology has trapped itself in the position where it has to attempt to measure zero.

We are in this morass because of our own default. Twenty years ago when we first detected the revolution which food technology was

[6] Arno Viehoever, "The Development of Daphnia Magna for the Evaluation of Active Substances," 109 *American Journal of Pharmacy* 360-366 (1937).

[7] A. C. Frazer, "Pharmacological Aspects of Chemicals in Food," 12 *Endeavour* 43-47 (1953).

to undergo, we did not start to lay the groundwork for a logical proof of safety. The pressure for a multitude of decisions on safety has led administrative agencies to rely upon the persuasive, but unsound, thesis that one can determine a "no-effect" level for rats, and that the susceptibility of a rat during its lifetime is equivalent to that of the human during his lifetime. Knowing full well that this thesis is untrue, we have all applied a very large safety factor in predicting the safe human intake. It seems that no harm has been done, but it is unsound to hide our eyes from the logical fallacy of our pragmatic course.

One component of our large safety factor is built into the units in which we express results, and hence is usually lost sight of. Equally sensitive tissues are injured by equal concentrations in the body fluids which bathe them. Equal concentrations result from equal dosages in grams per kilo. If rat and man are equally sensitive, they can each tolerate without effect the same grams-per-kilo-per-day intake. When we pass from the rat "no-effect" dose to the human "safe dose" we speak of p.p.m. [parts per million] in the diet of each. The calorific needs of small animals, due to the surface volume ratio of their bodies, are greater than those of large animals in terms of body weight. They eat more. One p.p.m. in the rat diet gives a grams-per-kilo intake of two to five times as much as one p.p.m. in the human diet. This ratio is implicit in our passage from rat to man, without being recognized as a component of the safety factor we discuss.

A Rational Alternative.—It is useful to speculate about how we would approach the evaluation of safety were we to undertake it as a new field of inquiry, unhampered by existing precedents, controversy and emotion. I believe we would plan work along the lines advocated by Barnes and Denz.[8] We would emphasize more than we do today the fact that every action of a compound is related to intake, both in intensity and in frequency of occurrence among a randomly selected population. The dosage-response curve would be a more real concept to us when we thought of chronic toxicity than it now is. With the usual experimental animals we would elucidate the characteristic physiological, biochemical and pathological actions of a compound, including the increase in effect which may accompany repetition of dosing. We would inquire whether these actions are similar for dif-

[8] Barnes and Denz, work cited at footnote 5.

erent species. We would determine a dosage-response curve for each action. At some low level of intensity, almost any adverse action is transient and reversible, hence can safely be produced experimentally in humans. If cancer is at issue, which we do not care to induce in humans, we would accept the animal curve without confirmation. For other actions we would induce the effect in humans at one or more low dosages, to determine relative species susceptibility. Then we would extrapolate the dosage-response curve to some low level of probable frequency, which informed opinion agreed corresponds to practical safety. This would define rather well the safe human intake of the additive, and comparison with the proposed intake would indicate safety or hazard of the proposal. This program would require profound thought and wide knowledge, but the actual work might be completed in a rather brief period.

Following a decision that a proposal would be safe to carry out, I think we would often provide for trial usage in a restricted area. The period of the trial would be varied to accord with the nature of an effect which excessive intake might produce. Some degree of clinical check upon health would be provided in the area of trial usage. If this trial period should prove consumer acceptance, utility of the additive, and presumptive confirmation of safety, general use might follow.

Some will object that we should not rely upon experimental animals at all, partly from their belief that we have no ethical right to use another species for our own ends, partly that we are never absolutely certain that animal reactions predict human reactions. It is a waste of time to speculate upon a purely human safety evaluation. I am convinced that we will never want to base evaluation solely upon human trials. To be fully satisfactory, such trials would require that humans be intentionally injured. Public enlightenment and private conscience would never permit this. We will never escape from some uncertainties about species differences. We can only reduce these by a positive experimental approach; we cannot eliminate them.

Public Scrutiny.—It is not enough that regulatory agencies should be convinced of the safety of a proposal to use an additive. The food processor himself has a major stake in the question of safety. He is responsible for the safety of his product. Reliance on private and public declarations by some authority is not an adequate defense

should some consumer claim injury. He must satisfy himself of the safety of what he proposes to do, and no legislation can remove that responsibility. He can do this only by examining carefully the bases upon which safety was evaluated, confirming by his own experiments any parts of the bases of which he himself is in doubt.

It is not only the food processor who should scrutinize the bases for a conclusion of safety of a proposed use of an additive. There are thousands of people who have some responsibility for preserving the public health, and other thousands with specialized knowledge which may be related to the question of safety. Each one of these should have an opportunity to bring his knowledge to bear in judging the soundness of a decision of safety. Only scrutiny by the entire scientific community can be relied upon to fill possible gaps in the knowledge of any individual and to assure fully informed proper decisions which can influence the safety of our diet. I believe that no additive should reach the general food supply until the proof of safety of its use has been published for study by everyone competent to judge the soundness of the decision to use it.

Speculation.—I conclude in a speculative vein. The open thermodynamic system which we call "life" must have arisen in a somewhat unfavorable environment. A limited homeostatic ability is characteristic of an open system. This ability has become more puissant as it has overcome an increasing variety of factors along the path of evolution. A generation ago Ellsworth Huntington pointed out that great civilizations have arisen only where meterological conditions produce a constantly fluctuating temperature and atmospheric violence. More recently, Arnold Toynbee has shown in more detail that every dominant culture has developed where a sufficient but not overwhelming challenge to success existed from the environment or from the neighbors. Every toxicologist who has administered an extended series of subacute or chronic dosages to animals has found a similar result. Often a certain dosage results in animals inferior to his control animals while some lower dosage results in animals better than his controls. I first found this many years ago with rats inhaling carbon tetrachloride vapors. Those breathing 50 p.p.m. were healthier, grew better and had more offspring than those inhaling no vapors.[9]

[9] H. F. Smyth, H. F. Smyth, Jr., and C. F. Carpenter. "The Chronic Toxicity of Carbon Tetrachloride; Animal Exposures and Field Studies," 18 *Journal of Industrial Hygiene & Toxicology* 277-298 (1936).

Such findings are too frequent in toxicological studies to result from the chance selection of inferior animals for the control group. They seem to be a manifestation of a general rule. Life seems to thrive upon frequent operation of its homeostatic protective mechanisms so long as the challenge is not great enough to overwhelm the defenses. Are we truly serving public health by trying to prevent ingestion of all compounds capable of causing an adverse effect? Perhaps the traces of harmful materials inevitably present in the purest obtainable food stuffs are enough to give the challenge to our defense mechanisms which we seem to require for abounding health. Perhaps the current better growth and improved health is partly due to the sufficient challenge to homeostasis of the traces of industrial products we receive every day. Is it possible that nutritionists will soon be advocating the controlled addition of substances to our food to replace the challenge which our ancestors received from the waste products of microorganisms, and which we now exclude by modern sanitation and packaging?

Summary.—In summary, we have today a widely followed and well-defined experimental technic for evaluating safety. It suffers from the necessity that we attempt the logically impossible task of proving a negative and it does not necessarily determine any important qualitative fact about the potentially injurious action of an additive. We attempt to compensate for the shortcomings of the technic—and for ignorance—by the use of a variable arbitrary safety factor. It is possible to plan a rational approach to safety evaluation consisting of experimental studies which can yield positive information, more valid in both a qualitative sense and a quantitative sense than are our present procedures. At the very least, we should provide for scrutiny by the entire scientific community of the basis for all decisions, to allow greater confidence in protection of public health.

UNITED STATES PHARMACOPOEIA REVISION ANNOUNCEMENT IS ISSUED

The sixth interim revision announcement applying to the *United States Pharmacopoeia,* XV Revision, has been issued, according to a newsbulletin release by the *Pharmacopoeia's* director of revision. Effective September 1, 1958, the announcement changed the listings of a number of drugs.

The entire text of the third, fourth, fifth and sixth interim revision announcements will be included in the *Second U. S. P. XV Supplement,* scheduled to be issued later this year.

Correspondence concerning the *United States Pharmacopoeia* may be addressed to its headquarters, 46 Park Avenue, New York 16, New York.

WASHINGTON—Continued from page 550

tive, including, where available, its chemical identity and composition;

"'(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

"'(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

"'(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"'(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"'(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

"'(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as compoents thereof, and of the food in or on which the additive is proposed to be used.

"'(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

"'Action on the Petition

"'(c) (1) The Secretary shall—

"'(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

"'(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"'(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"'(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

"'(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

"'(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

"'(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

"'(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

"'(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

"'(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"'(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

"'(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

"'(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

"'Regulation Issued on Secretary's Initiative

"'(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

"'Publication and Effective Date of Orders

"'(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

"'Objections and Public Hearing

"'(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

"'(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

"'(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier

effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"'Judicial Review

"'(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"'(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"'(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

"'(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"'(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

"'Amendment or Repeal of Regulations

"'(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

"'Exemptions for Investigational Use

"'(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.'"

"SEC. 5. Section 301(j) of such Act is amended by inserting '409', after '404,'.

"SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment.

"(b) Except as provided in subsection (c) of this section, section 3 of this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

"(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

"(1) either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective,

"whichever date first occurs.

"SEC. 7. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

"SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be $20,000.

"SEC. 9. Section 208(g) of the Public Health Service Act, as amended (42 U. S. C. 210(g)), is amended by striking out the phrase 'in the professional and scientific service' and inserting in lieu thereof the phrase 'in the professional, scientific, and executive service' and by striking out the phrase 'of specially qualified scientific or professional personnel' and inserting in lieu thereof 'of specially qualified scientific, professional, and administrative personnel'.

"Approved September 6, 1958."

In the Federal Trade Commission

Federal Trade Commission Act Section 5(a)(6) Amended.—Public Law 85-909 has given the Federal Trade Commission new jurisdiction over certain practices in the meat-packing industry. The amendment made by the new law, enacted September 2, struck out the phrase "persons, partnerships or corporations subject to the Packers and Stockyards Act, 1921, except as provided in section 406(b) of said Act" in FTC Act Section 5(a)(6) and substituted the phrase "persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 406(b) of said Act."

In general, the new law gives the FTC jurisdiction over all transactions in oleomargarine and over retail sales of meat, meat-food products, livestock products in unmanufactured form, and poultry products. However, under certain circumstances, the Secretary of Agriculture also has jurisdiction over such transactions. Also, under certain circumstances, the FTC has jurisdiction over nonretail transactions involving such products.

Pricing Guide Proposed.—According to a recent FTC release, an eight-point guide on fictitious pricing methods has been formulated by the Commission's staff and presented to the full Commission for approval. This guide, if approved, will offer merchants a clear-cut warning on what kinds of price advertising violate the law.

HAWAII'S FOOD-DRUG LAWS—Continued from page 563

APPENDIX

Session Laws 1898

An Act to Provide Against the Adulteration of Food and Drugs[1]

"Be it enacted by the Legislature of the Republic of Hawaii:

"SECTION 1. That no person shall, within the Republic of Hawaii, manufacture, offer for sale, or sell any drug or article of food which is adulterated, within the meaning of this Act.

"SECTION 2. The term 'drug', as used in this Act, Shall include all drugs, medicines or medicinal preparations for internal or external use, antiseptics, antiseptic dressings, disinfectants and cosmetics. The term 'food', as used herein, shall include all articles used for food or drink by man, whether simple, mixed or compound.

"SECTION 3. An article shall be deemed to be adulterated within the meaning of this act:

"(a) In the case of drugs:

"(1) If, when sold under or by a name recognized in the United States Pharmacopoeia, it differs from the standard of strength, quality or purity laid down therein; (2) If, when sold under or by a name not recognized in the United States Pharmacopoeia, but which is found in some other Pharmacopoeia, or other standard work on materia medica, it differs materially from the standard of strength, quality or purity laid down in such work; (3) If its strength, quality or purity falls below the professed standard under which it is sold; (4) If it contains any substance inimical or dangerous to life without the same being duly stated on the label or wrapper.

"(b) In the case of food:

"(1) If any substance or substances have been mixed with it, so as to lower or depreciate, or injuriously affect its quality, strength or purity; (2) If any inferior or cheaper substance or substances have been substituted, wholly or in part, for it; (3) If any valuable or necessary constituent or ingredient has been wholly or in part abstracted from it; (4) If it is an imitation of, or is sold under the name of another article; (5) If it consists, wholly or in part, of a diseased, decomposed, putrid, infected, tainted or rotten animal or vegetable substance or article, whether manufactured or not—or, in the case of milk, if it is the produce of a diseased animal; (6) If it is colored, coated, polished or powdered, whereby damage or inferiority is concealed, or if by any means, it is made to appear better or of greater value than it really is; (7) If it contains any added substance or ingredient which is poisonous or injurious to health, or any deleterious substance not a necessary ingredient in its manufacture: Provided that the provisions of this Act shall not apply to mixtures or compounds recognized as ordinary articles of food, if the same be distinctly labeled as mixtures or compounds, and are not injurious to health, and contain no ingredient not necessary to the preparation of a genuine article of such mixtures or compounds, and from which no necessary ingredient in its preparation is eliminated.

[1] At the first session of the Legislature of the Territory of Hawaii in 1901, Act 34 was amended by substituting the word "Territory" for "Republic" wherever it occurred.

"SECTION 4. Every person manufacturing, offering or exposing for sale, or delivering to a purchaser, any drug or article of food, included in the provisions of this Act, shall furnish to the duly appointed Food Commissioner, upon demand, either personal or in writing, a sample sufficient for the analysis of any such drug or article of food which is in his possession.

"SECTION 5. Whoever refuses to comply, upon demand, with the requirements of Section 4, and whoever violates any of the provisions of this Act, shall be guilty of a misdemeanor, and, upon conviction, shall be fined not exceeding one hundred, nor less than twenty-five dollars, or imprisoned at hard labor not exceeding one hundred nor less than thirty days, or both. And any person found guilty under the provisions of this Act, of manufacturing, offering for sale or selling an adulterated article of food, or drug, shall be adjudged to pay, in addition to the penalties hereinbefore provided for, all the necessary expenses incurred in inspecting and analyzing such adulterated articles, of which said person may have been found guilty of manufacturing, selling or offering for sale.

"SECTION 6. To carry out the provisions of this Act, the Board of Health shall appoint a duly qualified Food Commissioner and Analyst, who shall receive such a salary as the Legislature shall from time to time appropriate and who shall furnish good and sufficient bonds of not less than Two Thousand Dollars ($2,000.00) for the proper and unprejudiced performance of his duties and who shall be provided by the Board of Health with the necessary chemical and microchemical apparatus, together with a proper office and laboratory for work.

"SECTION 7. It shall be the duty of the Food Commissioner to carefully inquire into the quality of the several articles, which are foods or the necessary constituents of foods, manufactured or for sale, or sold or exposed for sale within the Republic of Hawaii, and he may in a lawful manner procure samples thereof, subject the same to careful examination and report the result of such analysis of all or any of such food and drink products, or dairy products, as are adulterated, impure or unwholesome, in contravention of the laws of the Republic of Hawaii, to the Board of Health, and it shall be the duty of the Food Commissioner, with the consent of said Board of Health, to make complaint, with the necessary evidence, through the proper authorities against such manufacturer or vendor.

"SECTION 8. The Food Commissioner, with the consent and sanction of the Board of Health, shall have power in the performance of his duties, to enter into any creamery, factory, store, salesroom, storageroom, drug store or laboratory, or any place where he has reason to believe food or drink are made, prepared, sold or offered for sale, and to open any cask, tub, jar, tin, bottle, case or package containing or supposed to contain any article of food or drink and examine or cause to be examined the contents thereof, and take therefrom samples for analysis.

"SECTION 9. The Food Commissioner shall make a monthly report in writing to the President of the Board of Health containing the results of inspection and analysis in detail; and upon the request of the said Board he shall furnish for publication a popular explanation of the same covering any month or period, together with any such other information, as may come to him in his official capacity relating to the adulteration of drugs and food and drink products, so far as the same may be deemed by said Board of Health to be of benefit and advantage to the public.

"SECTION 10. The Food Commissioner shall investigate complaints on the information of any person, who shall lay before him satisfactory evidence of the same.

"SECTION 11. Jurisdiction is hereby conferred upon all District Magistrates to hear and determine all cases arising under this Act.

"SECTION 12. This Act shall take effect and be in force from and after its publication.

"Approved this 16th day of May, A. D. 1898.

"SANFORD B. DOLE,
"President of the Republic of Hawaii"

From Laws of the Republic of Hawaii
Session of 1898

SECRETARY FLEMMING SUMMARIZES RADIOLOGICAL HEALTH ACTIVITIES BY FDA

On September 22, Arthur S. Flemming, Secretary of Health, Education, and Welfare, in a news-conference release, noted the variety of significant activities underway in the Food and Drug Administration helping to lay a foundation for public-health protection in the future atomic age. At the same time, he released summaries of the development of programs in this area by both FDA and the United States Public Health Service. The summary relating to radiological health activities of FDA included the following information:

In 1951, FDA initiated a training program on radiation fundamentals and methods of detecting radiation in food and drug products. Four teams of instructors each visited four FDA districts and gave one-week courses. Some 400 federal, state and local food and drug personnel received this training. The following year, equipment purchases were begun to provide each district with instruments for monitoring supplies and to equip a small laboratory in FDA's Division of Pharmacology in Washington.

Scientists of FDA, in 1953, conducted experiments at the Nevada proving ground to determine effects of an atomic explosion on drugs. It was found that where packages were left intact, there was little adverse effect on contents except for initial radioactivity, which might make immediate use of some drugs subject to question and for a reduction in potency of insulin and vitamin B_{12}.

The first large-scale radiological examination of food began in March, 1954, when entries of frozen Pacific tuna at United States ports were checked with Geiger counters in a continuous program. Examination of every fish continued until early in May, 1954, when operations were reduced to a spot-check basis. In the same year—under Delegation No. 1 from the Federal Civil Defense Administration—FDA was assigned to "plan a national program, conduct research, develop technical guides for States, and direct Federal activities designed to meet the extraordinary needs for food and drug inspection and control in attacked areas."

Other highlights of activities by the Administration from 1955 into 1958 included resumption of the training program; extensive experiments at the Nevada test site; appointment by the National Research Council —at FDA request—of a Civil Defense Foods Advisory Committee; comparison of foods packed prior to 1945 with foods packed in subsequent years; studies of contamination by fall-out; and responsibilities directed towards the recent passage by Congress of the food-additive amendment, which includes a requirement that any radioactive materials used in food-processing be classed as food additives.

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